e-ISSN:2602-2079

Volume 9
Issue 11
2025

JOURNAL of Surgery and Medicine

International Medical Journal

JOSAM

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Published: 2025-11-29

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J Surg Med. 2025;9(11):222-224.
https://doi.org/10.28982/josam.8205

JOSAM

Research article
https://jsurgmed.com/

Journal of Surgery and Medicine

e-ISSN: 2602-2079

Colorectal malignancy in the younger non-screened age group – A national study

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Ethics Committee Approval
Permissions and approvals from the Data Protection Review Unit and the General Surgical Department at Mater Dei Hospital (Malta) were obtained for data analysis of non-identifiable data. All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2025 October 30

Abstract

Background/Aim: Colorectal cancer (CRC) continues to be a significant public health issue. There is growing concern that the incidence rate for CRC in adults under 55 years of age is on the rise. This study aimed to identify the trends in incidence rates for CRC cases among the non-screened adult population.
Methods: All patients, aged between 18 and 55 years, who were diagnosed and underwent colorectal resections for histologically confirmed CRC between January 2010 and December 2023, were identified and included in the data set.
Results: A total of 162 patients under the age of 55 were diagnosed and operated on for CRC, with an even gender distribution of 81 males (50%) and 81 females (50%). The median age was 44 years (range: 18 to 55 years). No significant statistical difference was detected between female and male patients in terms of median age (P=0.41), both had a median age of 45 years. The total amount of CRC tumors diagnosed per year in patients under 55 averaged about 12.00 cases (mean=11.58 cases per year). There appeared to be a slight trend of increasing incidence by 0.36 cases per year. No significant statistical differences were found in relation to tumor location, tumor stage, and gender (P=0.93, P=0.11). The median survival period was 32.15 months (range: 1–112 months).
Conclusion: The incidence of CRC in younger, non-screened patients was found to be on the rise in our local population. Clinicians need to be vigilant for CRC in younger individuals. Additionally, early investigations may need to be undertaken within this age group.

Keywords: screening, colorectal, cancer, population

How to cite: Sammut M, Sammut M, Farrugia M, Gatt J, Spiteri N, Gatt N. Colorectal malignancy in the younger non-screened age group – A national study. J Surg Med. 2025;9(11):222-224.

Introduction

In the European Union (EU), colorectal cancer (CRC) is the second most frequently diagnosed cancer, following breast cancer, and is cited as the second leading cause of cancer-related mortality, after lung cancer. The EU's standardized death rate for CRC stands at 29.7 per 100,000 population, highlighting that CRC remains a significant public health issue. Among EU Member States, the standardized death rates for CRC are higher in male patients compared to female patients [1].

Although CRC cancer cases are being identified through population screening programs, there is growing public health concern that the incidence rate for adults aged under 55 years with CRC has increased [2-4]. The objective of this study was to determine incidence rate trends in CRC cases in the local adult population that has not been screened.

Materials and methods

Permissions and approvals for data analysis of non-identifiable data were obtained from the Data Protection Review Unit and the General Surgical Department at Mater Dei Hospital (Malta). All patients aged between 18 and 55 years who were diagnosed with and had undergone colorectal resections for histologically confirmed CRC between January 2010 and December 2023 were identified and included in the dataset. These patients were identified from prospectively maintained CRC histology and theatre databases. A retrospective data analysis of this dataset was conducted. Staging of CRC utilized computed tomography (CT), magnetic resonance imaging (MRI), and histology results. Collected data comprised age at presentation, demographics, CRC stage at presentation, tumor location, and mortality.

Statistical analysis

Results were analyzed using SPSS version 21.0, and a p-value of less than 0.05 was considered statistically significant. Continuous variables were evaluated using the unpaired Student's t-test, while the Chi-square and Fisher tests were employed for categorical variables. The study was conducted in accordance with the STROBE guidelines [5].

Results

From 2010 to 2023, a total of 162 patients under the age of 55 were diagnosed and treated for CRC, evenly split between males (81 or 50.00%) and females (81 or 50.00%). There was no significant statistical difference (P=0.41) between the median age of female patients (45 years) and male patients (45 years) at their initial CRC presentation (Table 1).

Figure 1 displays the total number of CRC cases per year in patients under the age of 55 (median=12.00 cases per year). Linear regression analysis indicates an overall trend of increasing CRC cases in the non-screened patient group, with an increase rate of 0.36 cases per year; however, this increase was not statistically significant (P=0.181).

There was no statistical difference in tumor location, tumor stage, and gender (P=0.93, P=0.11) (Table 2 and Table 3).

The median survival was 32.15 months (range=1–112 months) for all CRC patients under the age of 55 years included in the dataset.

Figure 1: Total CRC cases detected and linear regression analysis.

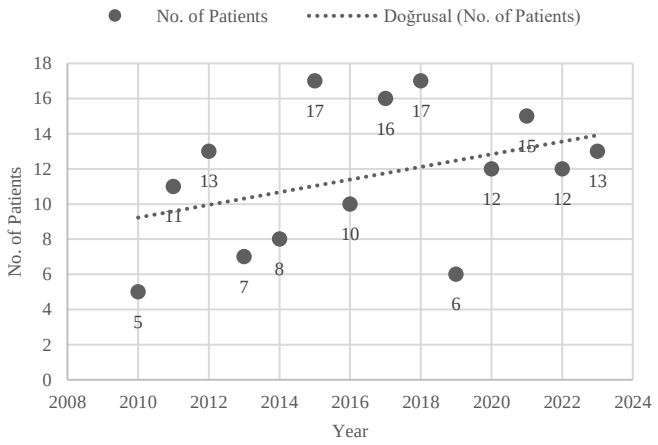

Table 1: Age range and gender differences.

Age Range (years)	Male (n (%))	Female (n (%))	Total (n (%))	*P*-value
20 - 24	1 (1.47)	0 (0.00)	1 (0.73)	1.00
25 - 29	2 (2.94)	3 (4.35)	5 (3.65)	1.00
30 - 34	6 (8.82)	10 (14.49)	16 (11.68)	0.42
35 - 39	15 (22.06)	13 (18.84)	28 (20.44)	0.66
40 - 44	14 (20.59)	13 (18.84)	27 (19.71)	1.00
45 - 49	41 (60.29)	34 (49.28)	75 (54.74)	0.33
50 - 54	2 (2.94)	8 (11.59)	10 (7.30)	0.09

Table 2: Colorectal cancer location and gender.

Tumor Location	Male (n (%))	Female (n (%))	Total (n (%))	*P*-value
Right-sided	11 (13.58)	13 (16.05)	24 (14.81)	0.82
Left-sided	30 (37.04)	32 (39.51)	62 (38.27)	0.86
Rectum	37 (45.68)	33 (40.74)	70 (43.21)	0.58
Anal	3 (3.70)	3 (3.70)	6 (3.70)	1.00

Table 3: Colorectal cancer stage and gender.

Tumor Stage at presentation	Male (n (%))	Female (n (%))	*P*-value
Stage 1	21 (25.93)	14 (17.28)	0.19
Stage 2	23 (28.40)	15 (18.52)	0.14
Stage 3	26 (32.10)	33 (40.74)	0.24
Stage 4	11 (13.58)	19 (23.46)	0.12

Discussion

Predictive population modeling suggests that there will be an increase from 4.8% (colon cancer) and 9.5% (rectal cancer) in 2010 to 10.9% (colon cancer) and 22.9% (rectal cancer) in 2030 among the non-screened younger age groups [6-7]. This has led to heightened public health concern due to the increasing incidence rate of CRC in these non-screened younger age groups [4,8-10].

Although CRC is more common in females above the age of 55 years, this study demonstrated an equal CRC incidence rate between females and males under the age of 55 years (P=0.41). A limitation of our study was that patients who were not operated on (e.g. due to inoperable CRC) were excluded. This exclusion may lead to an underestimation of the rising incidence of CRC malignancies in the younger patient age group. Furthermore, the CRC incidence in the non-screened group may be underestimated due to missing data and selection bias related to retrospective studies.

The increasing prevalence of CRC in younger patients necessitates further research to ascertain the causes of this rise [12]. Although most CRC cases in youthful patients are presumed to be sporadic, environmental factors likely play a part [3]. Cohort and case-control studies have identified modifiable risk factors such as obesity, smoking, heavy alcohol consumption, insufficient physical activity, and a diet high in meat but low in fiber [8,12-14].

One implication of the increasing incidence rate in the younger, non-screened group is the recommendation to initiate CRC population screening programs at an earlier age both locally

and in several countries worldwide [4]. However, there is limited data on screening patients below the age of 55, as the total number of CRC cases in younger patients remains low. This scarcity incites questions about the cost-effectiveness and increasing demand for endoscopy suites related to lowering the age for screening programs [2,15]. Screening individuals with risk factors, such as a positive family history, may be effective, yet further studies are required to stratify risk among young patients [7,10,12].

Limitations

One limitation of our study is that it excluded patients who were not operated on, such as those with inoperable CRC. However, it is important to note that this was a retrospective study, subject to the limitations of data bias.

Conclusion

In conclusion, we found an increasing incidence of CRC in the younger non-screened patient group within our local population. If this rise persists, it may necessitate further studies in risk stratification and a reconsideration of current CRC screening practices. It is crucial to heighten clinicians' awareness of CRC in younger patients and we may need to consider early investigations in this age group.

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J Surg Med. 2025;9(11):225-229.
https://doi.org/10.28982/josam.8339

JOSAM

Journal of Surgery and Medicine

e-ISSN: 2602-2079

Research article
https://jsurgmed.com/

Comparative performance analysis of two matrix-assisted laser desorption/ionization time-of-flight mass spectrometry systems for direct identification of urinary tract pathogens from clinical samples

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Ethics Committee Approval
The study was approved by the institutional ethics committee of Erciyes University Faculty of Medicine (approval number 2025/270).
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2025 October 30

Abstract

Background/Aim: Urinary tract infections (UTIs) are a significant global health concern that necessitates expedited diagnostic methods to guide appropriate antimicrobial treatment and mitigate the spread of multidrug-resistant organisms. This investigation was conducted to assess the effectiveness of two distinct matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS) platforms for the direct identification of UTI-causing agents from urine samples: VITEK MS (bioMérieux, France) and MALDI Biotyper Sirius (Bruker Daltonics, Germany). The findings were evaluated by comparison of the outcomes with those of conventional urine culture, which is considered the diagnostic gold standard.
Methods: The study included 60 urine specimens consisting of 40 specimens from patients presenting with UTI symptoms and 20 specimens from a control group that showed no bacterial growth in culture. A differential centrifugation method was employed to prepare the samples, which were subsequently analyzed using both MALDI-TOF MS systems. Concurrently, all samples underwent conventional urine culture.
Results: Among the 40 culture-positive samples, the MALDI Biotyper Sirius system demonstrated an overall identification sensitivity of 69.2% and a specificity of 95.2%. The VITEK MS system showed a sensitivity of 79.5% and a specificity of 95.2%. For the 29 samples with a bacterial concentration of ≥1×105 colony-forming units per milliliter (CFU/mL), the sensitivity was 75.9% for the MALDI Biotyper Sirius system and 79.3% for the VITEK MS system. A statistical evaluation using McNemar's test determined that the difference in sensitivity between the two platforms was not statistically significant (P=0.125).
Conclusion: The findings suggest that both MALDI-TOF MS platforms have considerable promise for the rapid and direct identification of uropathogens, particularly in monomicrobial urine samples with a high bacterial load (≥1×105 CFU/mL). While the VITEK MS system exhibited a marginally higher overall identification sensitivity, the data indicate that both systems can be considered valuable assets in clinical diagnostic laboratories.

Keywords: urinary tract infection, MALDI-TOF MS, VITEK MS, MALDI Biotyper Sirius, uropathogen, rapid diagnosis

How to cite: Ertürk Melez M, Atalay MA, Sağıroğlu P, Mutlu Sarıgüzel F. Comparative performance analysis of two matrix-assisted laser desorption/ionization time-of-flight mass spectrometry systems for direct identification of urinary tract pathogens from clinical samples. J Surg Med. 2025;9(11):225-229.

Introduction

Urinary tract infection (UTI) is a frequently occurring bacterial condition that poses a substantial public-health challenge and impacts an estimated 150 million individuals globally each year. The clinical manifestations of UTIs vary widely, ranging from uncomplicated cases of cystitis to severe life-threatening conditions, such as uroseptic shock [1–3]. Uropathogenic *Escherichia coli* is the primary causative agent and accounts for over 80% of community-acquired UTI cases. Other significant pathogens include *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus saprophyticus*, *Enterococcus faecalis*, *Streptococcus agalactiae*, and *Candida* species, of which the latter three are particularly relevant in healthcare-associated infections [3].

Conventional urine culture is the long-established benchmark for identifying urinary pathogens, but it is a labor-intensive and time-consuming process. In a typical microbiology laboratory, pathogen identification can take between 18 and 48 hours, and an additional 18 to 24 hours are required for antimicrobial susceptibility testing [3]. This extensive diagnostic timeline has direct clinical consequences and often leads to the prescription of empirical broad-spectrum antibiotics, which may not be appropriate for the specific pathogen. Over-prescription of such agents can delay effective treatment and, more critically, contribute to the selective pressure and proliferation of multidrug-resistant microorganisms. Consequently, there is an increasing necessity for expedited diagnostic techniques that can provide rapid pathogen identification and enable more timely antimicrobial susceptibility results [2,3].

Matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS) has emerged as a standard rapid method for bacterial identification from cultured colonies in many clinical microbiology settings. Furthermore, the technique has promise for direct identification from biological samples, such as urine. The direct analysis of clinical specimens is more challenging due to several inherent constraints. These limitations include the requirement of a sufficient number of microbial cells, an adequate sample volume, and a pre-analytical preparation protocol to address the presence of host cells, proteins, and other interfering biological components [4].

Despite these challenges, numerous studies have demonstrated that MALDI-TOF MS can provide reliable and swift detection of bacterial pathogens directly from urine [4–6]. The present study was designed to specifically evaluate the performance of two prominent commercial MALDI-TOF MS platforms, VITEK MS and MALDI Biotyper Sirius, for the direct identification of urinary tract pathogens from urine samples. The results were directly compared with those of conventional culture methods, which served as a reference standard.

Materials and methods

Study design and ethical considerations

Urine specimens were prospectively gathered from the Bacteriology Unit of the Central Laboratory at Erciyes University Faculty of Medicine. The sample cohort included 40 specimens from inpatients and outpatients with suspected UTI symptoms, as well as 20 control samples that were found to have no microbial growth in culture. For inclusion in the study, samples were required to contain bacteria or yeast and show no indication of polymicrobial growth, which was visually confirmed by Gram staining and microscopic examination. The study protocol was approved by the institutional ethics committee of Erciyes University Faculty of Medicine (approval number 2025/270) and was conducted with strict adherence to the Declaration of Helsinki. A waiver of informed consent was granted by the ethics committee as the study utilized de-identified residual clinical samples, which ensured complete patient privacy and confidentiality.

Sample preparation and identification

A differential centrifugation protocol was employed to prepare the samples for mass spectrometry. First, 4 mL of each urine specimen were initially centrifuged at 2,000 × *g* for 30 seconds to separate host cells and cellular debris such as leukocytes into a pellet. This process led to enrichment with microbial cells with reduced host interference in the supernatant, which was collected and subjected to high-speed centrifugation at 15,500 × *g* for 5 minutes to concentrate the microorganisms into a pellet. The resulting microbial concentrate was then purified by a single wash cycle using deionized water.

For direct and parallel evaluation of the two systems, the isolated microbial pellet from each specimen was divided into two equal portions, and one was used for the VITEK MS system, while the other was used for the MALDI Biotyper Sirius system. This step was crucial to ensure a fair comparison by eliminating any pre-analytical variability between the two platforms. The rationale for the differential centrifugation protocol, particularly the initial low-speed centrifugation step, was to minimize the impact on the MALDI-TOF MS analysis by host cells and debris, such as leukocytes. While we did not perform a separate optimization study, this step is a key component of established protocols in the literature aimed at increasing the ratio of bacterial cells to host cells and improves the quality of the protein spectra and identification scores.

Identification with VITEK MS

A small portion of the prepared pellet was applied as a thin layer onto a VITEK MS target spot (bioMérieux, France) and allowed to air-dry completely. Following the initial drying step, 1 µL of an α-cyano-4-hydroxycinnamic acid (HCCA) matrix solution was placed on top of the sample and left to dry at room temperature. The prepared target spots were then loaded into the VITEK MS instrument for analysis. Quality control and calibration were performed using the standard strain *E. coli* ATCC 8739.

Identification with MALDI Biotyper Sirius

A small quantity from the same microbial pellet was also applied as a thin film onto a MALDI Biotyper Sirius plate (Bruker Daltonics, Germany). After the sample had dried, 1 µL of a 70% formic acid solution was added to facilitate protein extraction and allowed to dry at room temperature. Next, 1 µL of the HCCA matrix solution was added. Once the spots had completely dried, the plates were loaded onto the MALDI Biotyper Sirius instrument for analysis. This system was also calibrated and subjected to quality control using the *E. coli* ATCC 8739 strain.

Table 1: Comparison of culture results and two different MALDI-TOF / MS system results for urinary tract pathogens identified from direct urine samples

No	Age	Gender	Service/Outpatient Clinic	Culture (CFU/mL)	MALDI Biotyper Sirius (Score)	Vitek MS (Score)
1	18	F	Emergency Medicine Outpatient Clinic	*E.coli* 100000	*E.coli* (2.29)	*E.coli* (99.9)
2	38	F	Urology Outpatient Clinic	*E.coli* 100000	*E.coli* (2.29)	*E.coli* (99.9)
3	61	F	Nephrology Outpatient Clinic	*E.coli* 100000	*E.coli* (2.28)	*E.coli* (99.9)
4	56	M	Urology Outpatient Clinic	*P.aeruginosa* 5.000	*M.morganii* (1.82)	Unidentified
5	80	F	Nephrology Outpatient Clinic	*E.coli* 100000	*E.coli* (2.19)	*E.coli* (99.9)
6	9	M	Pediatric Nephrology Unit	*K.pneumoniae* 100000	*K.pneumoniae* (2.17)	*K.pneumoniae* (99.9)
7	1	F	Pediatric Nephrology Outpatient Clinic	*E.coli* 100000	Unidentified	Unidentified
8	65	F	Nephrology Outpatient Clinic	*E.coli* 50000	*E.coli* (1.88)	*E.coli* (99.9)
9	79	F	Oncology Service	*E.coli* 100000	Unidentified	Unidentified
10	84	F	Nephrology Service	*E.coli* 100000	*E.coli* (2.17)	*E.coli* (99.9)
11	55	M	Urology Service	*E.coli* 10000	*E.coli* (2.29)	*E.coli* (99.9)
12	7	F	Pediatric Nephrology Outpatient Clinic	*E.coli* 100000	*E.coli* (2.36)	*E.coli* (99.9)
13	17	F	Pediatric Nephrology Outpatient Clinic	*E.coli* 100000	Unidentified	Unidentified
14	61	F	Nephrology Outpatient Clinic	*K.pneumoniae* 100000	*K.pneumoniae* (2.12)	*K.pneumoniae* (99.9)
15	76	F	Nephrology ICU	*C.albicans* 100000	Unidentified	*C.albicans* (99.9)
16	8	F	Urology Outpatient Clinic	*E.coli* 100000	*E.coli* (2.24)	*E.coli* (99.9)
17	79	F	Oncology Service	*E.coli* 100000	*E.coli* (2.12)	*E.coli* (99.9)
18	81	M	Gastroenterology Service	*C.albicans* 100000	Unidentified	Unidentified
19	12	F	Pediatric Nephrology Outpatient Clinic	*E.coli* 100000	*E.coli* (2.14)	*E.coli* (99.9)
20	64	F	Nephrology Outpatient Clinic	*E.coli* 100000	Unidentified	Unidentified
21	61	M	Internal Medicine ICU	*K.pneumoniae* 100000	*K.pneumoniae* (2.12)	Unidentified
22	66	F	Nephrology Outpatient Clinic	*E.coli* 50000	Unidentified	*E.coli* (99.7)
23	73	F	Gastroenterology Service	*E. faecium* 10000	Unidentified	Unidentified
24	44	F	Endocrinology Service	*E.coli* 100000	*E.coli* (2.20)	*E.coli* (99.9)
25	51	M	Urology Outpatient Clinic	*E.coli* 100000	*E.coli* (2.17)	*E.coli* (99.9)
26	21	M	Infectious Diseases Outpatient Clinic	*E.coli* 100000	*E.coli* (2.26)	*E.coli* (99.9)
27	2	F	General Pediatrics	*P.mirabilis* 100000	*P.mirabilis* (2.21)	*P.mirabilis* (99.9)
28	54	F	Infectious Diseases Outpatient Clinic	*E.coli* 100000	*E.coli* (2.31)	*E.coli* (99.9)
29	29	F	Obstetrics and Gynecology Service	*P.mirabilis* 50000	*P.mirabilis* (2.01)	*P.mirabilis* (99.9)
30	70	F	Nephrology Outpatient Clinic	*E.coli* 1000	*E.coli* (2.26)	*E.coli* (99.9)
31	50	M	Urology Outpatient Clinic	*E.coli* 100000	*E.coli* (2.06)	*E.coli* (99.9)
32	5	M	Urology Service	*K.pneumoniae* 100000	*K.pneumoniae* (2.12)	*K.pneumoniae* (99.9)
33	73	M	Urology Outpatient Clinic	*K.pneumoniae* 100000	*K.pneumoniae* (2.01)	*K.pneumoniae* (93.1)
34	27	F	Infectious Diseases Outpatient Clinic	*E.coli* 5000	*E.coli* (2.35)	*E.coli* (99.9)
35	10	F	Pediatric Hematology and Oncology Service	*E.coli* 100000	*E.coli* (2.11)	*E.coli* (99.9)
36	76	M	Urology Outpatient Clinic	*A. xylosoxidans* 50000	*A. xylosoxidans* (1.91)	*A. xylosoxidans* (99.9)
37	7	M	Pediatric Nephrology Outpatient Clinic	*K.pneumoniae* 100000	Unidentified	*K.pneumoniae* (93.1)
38	73	M	Nephrology Outpatient Clinic	*E.coli* 100000	Unidentified	*E.coli* (99.9)
39	1	M	Pediatric Emergency	*E.faecium* 10000	Unidentified	*E.faecium* (99.9)
40	68	M	Urology Outpatient Clinic	*E.coli* 5000	Unidentified	*C.freundii* (99.5)

Urine culture

All urine specimens were concurrently subjected to conventional urine culture, which served as the reference method for pathogen identification. The reliability of the culture and identification procedures was ensured by using control strains, including *E. coli* ATCC 25922 and *P. aeruginosa* ATCC 27853 (American Type Culture Collection, Manassas, VA, USA). The samples were incubated in an aerobic environment containing 5% carbon dioxide at 37°C for 18–24 hours. Any colonies on the plates that exhibited significant growth were then identified using the MALDI Biotyper Sirius system (Bruker Daltonics, Germany).

Statistical analysis

Statistical analyses were performed using the software SPSS Statistics version 20.0 (IBM, Corp., NY, USA). The performance metrics of the diagnostic tests included the sensitivity and specificity values, as well as the corresponding 95% confidence intervals (CIs). The paired diagnostic performance of the two MALDI-TOF MS systems was compared using McNemar's test.

Results

The study population comprised patients with an average age of 45.3 years. The most common bacterial species isolated from the samples was *E. coli*, which was identified in 26 patients. The overall performance of the two MALDI-TOF MS systems for direct pathogen identification was assessed against the conventional culture method. As shown in Table 1, the MALDI Biotyper Sirius system yielded a sensitivity of 69.2% (95% CI: 52.4–83.0%) and a specificity of 95.2% (95% CI: 76.2–99.9%). In contrast, the VITEK MS system demonstrated a sensitivity of 79.5% (95% CI: 63.5–90.7%) and a specificity of 95.2% (95% CI: 76.2–99.9%). The statistical comparison of the overall sensitivities using McNemar's test indicated that the observed difference was not statistically significant (P=0.125).

A subset analysis was conducted on the 29 urine specimens with a bacterial load of ≥1×105 CFU/mL. In this group, the identification sensitivity of the MALDI Biotyper Sirius system was 75.9% (95% CI: 56.4–89.7%), while that of the VITEK MS system was 79.3% (95% CI: 60.3–92.0%).

Inconsistent results were noted in several samples, particularly those with a lower bacterial count. For instance, a sample with 5,000 CFU/mL of *P. aeruginosa* (Sample 4) was not identified by the VITEK MS system, while the MALDI Biotyper Sirius system incorrectly identified it as *Morganella morganii*. Similarly, in a sample with 5,000 CFU/mL of *E. coli* (Sample 40), the MALDI Biotyper Sirius system failed to provide an identification, whereas the VITEK MS system provided an erroneous identification of *Citrobacter freundii*.

The differential centrifugation protocol proved effective and enabled direct identification of the most common UTI pathogens with both systems. While both platforms performed similarly on high-titer samples (≥1×105 CFU/mL), the VITEK MS system demonstrated a marginally higher overall identification sensitivity across the entire sample set. The complete comparative data for all samples are presented in Table 1.

Discussion

The central objective of this study was to perform a direct comparative evaluation of the performance of two widely used commercial MALDI-TOF MS systems, the MALDI Biotyper Sirius and the VITEK MS, for the rapid identification of bacterial pathogens directly from urine samples. Previous research has already established the better performance of MALDI-TOF MS over conventional methods for identifying microorganisms from colonies grown on culture media [7–10], but the present work provides a focused head-to-head comparison of these two major platforms under identical clinical conditions.

Our findings confirm the robust performance of both systems, particularly for the identification of Gram-negative bacteria, which are the most frequent causative agents of UTIs. High sensitivity of 79.3% for the VITEK MS system and 75.9% for the MALDI Biotyper Sirius system was obtained in monomicrobial urine samples with a high bacterial load of ≥1×105 CFU/mL. These results are consistent with the range of 67% to 86.6% reported in the literature for direct urine analysis using this technology [5,11–13]. Our data support the findings of Zboromyrska et al. [4], who reported a similar success rate of 72.8% in a multicenter study, which further supports the clinical utility of this approach. The alignment of our findings with previous research validates the method's potential as a reliable tool for quick UTI diagnosis, particularly for specimens with a high concentration of microorganisms.

This study also highlights several persistent limitations of direct MALDI-TOF MS analysis that have been documented previously. A significant technical constraint is the dependency on a sufficient microbial load. The performance of both systems was noticeably decreased when analyzing samples with low bacterial density. This observation reinforces the findings of other researchers who have proposed that direct identification from urine is most successful when the bacterial concentration exceeds 1×105 CFU/mL [14]. Given these outcomes, the bacterial count of ≥5,000 CFU/mL used in this study could serve as a practical threshold for pre-selecting samples for rapid analysis, as suggested by other investigators [3,4,15]. This approach would not only optimize the method's sensitivity but also streamline laboratory workflows by prioritizing the most promising samples for rapid testing.

Another critical challenge was the difficulty in identifying yeast species. This is consistent with prior research reporting low identification rates for yeasts [6,16]. In our analysis of two urine samples that were culture-positive for *Candida albicans*, only one was correctly identified by the VITEK MS system, and neither was identified by the MALDI Biotyper Sirius system. In such instances, MALDI-TOF MS may provide identification at only the genus level or no result at all, thus providing limited useful information for clinicians. This enduring challenge suggests that the unique protein profiles or cell-wall compositions of yeasts may be less amenable to current direct-identification protocols and highlights the continued necessity of conventional culture methods for the definitive diagnosis of yeast-related UTIs [3].

Conclusions

This study has demonstrated that MALDI-TOF MS using the VITEK MS and MALDI Biotyper Sirius systems provides a valuable and rapid alternative for the direct identification of uropathogens from high-titer urine samples. Both platforms exhibited acceptable sensitivity in monomicrobial samples with a bacterial load of ≥1×105 CFU/mL. While the VITEK MS system showed a slightly higher overall identification performance, the statistical analysis determined that the difference was not significant. From a clinical perspective, this non-significant difference suggests that the selection between these two powerful systems for a laboratory setting would likely be based on practical considerations beyond performance, such as cost per test, ease of integration with existing systems, or the size and scope of their respective protein databases.

The findings affirm the clinical utility of direct MALDI-TOF MS analysis as a powerful tool for accelerating UTI diagnosis, particularly for cases with a high bacterial count. However, the persistent limitations of this method in identifying pathogens in low-density samples and the consistent challenges with yeast species underscore key areas for future research. Future studies should concentrate on optimizing the sample-preparation protocols by exploring advanced enrichment or concentration techniques to enhance sensitivity across all bacterial loads. Furthermore, continued efforts to improve the protein databases and algorithms will be essential to expand the routine use of MALDI-TOF MS for a broader spectrum of microorganisms, which could ultimately improve the speed and accuracy of UTI diagnosis.

Acknowledgements

We extend our sincere appreciation to Mustafa Baysan, Pınar Yaşar, Kasım Karacagil, Dinçer Koc, Gülsah Koc, and Burcu Boyraz for their invaluable assistance and expertise in performing the MALDI-TOF analyses, which were crucial to the successful completion of this work.

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J Surg Med. 2025;9(11):230-234.
https://doi.org/10.28982/josam.8192

JOSAM

Research article
https://jsurgmed.com/

Journal of Surgery and Medicine

e-ISSN: 2602-2079

A 10-year single-center audit of cell saver use in cardiac surgery

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Abstract

Background/Aim: The use of cell saver technology has revolutionized the management of blood in cardiac surgery, with the objective of reducing the need for allogeneic blood transfusions and enhancing patient outcomes. This study presents a 10-year audit of cell saver use in cardiac surgeries at a tertiary cardiothoracic center in Scotland.

Methods: An analysis of data from cardiac surgery cases using cell savers was conducted. The study assessed the quantity of anticoagulant used, the processing of blood, and the recovery of red blood cells.

Results: The center consistently employed heparin as the anticoagulant during the review period. The mean age of the 1717 patients was 56.85 years; 66.86% were male and 33.14% were female. The mean blood processed volume was 1646.55 ml and the mean salvaged red cell volume was 544.22 ml over a 10-year period. The deployment of cell savers was most prevalent during coronary artery bypass graft surgeries and major aortic procedures.

Conclusion: The potential to minimize blood loss and reduce allogeneic blood transfusions is present in cell saver technology for cardiac surgery. The significance of optimizing cell saver protocols to enhance patient care and efficacy is underscored in the study.

Keywords: cell saver, cardiac surgery, transfusion

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Ethics Committee Approval
The study was approved by the Institutional Review Board of Golden Jubilee National Hospital (approval number 2087).
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2025 November 5

How to cite: Otorkpa MJ, Mahmood Z. A 10-year single-center audit of cell saver use in cardiac surgery. J Surg Med. 2025;9(11):230-234.

Introduction

Over the past decade, cell salvage techniques in cardiac surgery have gained attention. This is due to its strategic role in patients for whom allogeneic blood transfusions are contraindicated. Allogeneic blood transfusions are vital to surgical procedures but come with risks and challenges. Thus, autologous blood donation before surgery and cell salvage methods to limit allogeneic blood product transfusion have become more popular.

The historical evolution of cell saver devices, especially in relation to perioperative care, represents a notable change in surgical strategies employed for blood conservation. Haemonetics unveiled the first commercial blood salvage device, the Cell Saver, in 1974 [1], therefore, marking a turning point in the discipline of transfusion medicine. The phrase "cell saver" has changed throughout time to refer to a larger class of blood salvage equipment used in different surgical environments, especially where significant blood loss is expected [2].

In cardiac surgery, cell saver technology has changed blood management to reduce allogeneic blood transfusions and improve patient outcomes. Cardiothoracic surgeries utilize a substantial portion of allogeneic red blood cells [3,4]. In the United Kingdom, roughly 10% of the blood supplied by the National Blood Service is used for cardiac surgery [5]. The state of intraoperative cell salvage use in cardiac surgery across the UK was highlighted by the 2021-2022 survey conducted by the UK Cell Salvage Action Group (UKCSAG) [6]. This survey aimed to evaluate existing practices and revealed that cell savers were widely utilized in various surgical specialties. In cardiac surgery, approximately 89% of responding cardiac units reported its use.

Cell-saver autologous blood transfusions involve obtaining and re-infusing the patient's blood either during or after surgery [7]. Many surgical disciplines, including cardiac surgery, orthopedics, and vascular surgery [1], find several benefits for this method.

Alternatives to homologous transfusions are needed due to fewer blood donors and rising blood product prices [5]. Blood conservation recommendations state that homologous blood transfusion in cardiac surgery is an established approach to lower blood loss [8]. The investigation of autologous blood donation, cell salvage technologies, and other blood management modalities has paved the way for the reduction of hazards associated with allogeneic blood transfusions, as well as the acquisition of a more thorough understanding of how to maximize patient outcomes. This 10-year review examines the use and efficacy of cell savers in cardiac procedures at a Scottish cardiothoracic institution.

Materials and methods

This retrospective analysis encompassed individuals who underwent cardiac surgery at a Scottish regional cardiothoracic center over a 10-year period. All patient data were processed in accordance with the Declaration of Helsinki and the UK National Health Service Research Ethics Committee standards. In order to safeguard the privacy of individuals, the investigation implemented rigorous anonymization protocols. This entailed the elimination of all identifiable information prior to data analysis and the assignment of unique identifiers while maintaining patient confidentiality. In accordance with the guidelines regulating retrospective data analysis, patient consent was waived in accordance with the NHS Health Research Authority policy for Scotland.

The audit included data from January 1, 2013 to January 1, 2023, with an emphasis on information gathered from the perfusion unit. Individuals who underwent cell salvage following cardiac surgical procedures met the inclusion criteria. Out of 2354 instances spanning a decade, 63 had missing data, 572 had insufficient volume processing (less than 600 ml for most cases), and three had red cells discarded owing to poor washing, leaving 1717 cases for final analysis.

The type of anesthesia employed, pulmonary artery catheterization, intraoperative monitoring measures, and transfusion strategy were all managed according to institutional standards. The operational roles for cell saver use in the institution were carried out by perfusionists and involved periodic evaluations and equipment checks. Heparin was always the preferred anticoagulant.

The audit team comprised a clinical teaching fellow (MO) and cardiac surgeon (ZM) with two perfusionists assisting in sourcing the data. The study focused on anticoagulant volumes, blood processing, and red cell salvage. The documentation also contained a breakdown of instances by year and the procedures used.

Statistical analysis

Statistical analysis was performed using Microsoft Excel (version 2010). Descriptive statistics were used to summarize patient characteristics, using mean, standard deviation, and percentage. A statistical significance value of <0.05 was used for two-tailed *P*-value.

Results

The study included and singularly audited a total of 1717 patients who underwent cardiac surgery over a 10-year period. Table 1 shows patients' sex and mean age. Of these patients, four were Jehovah's Witnesses, who typically refuse consent for blood transfusion due to religious reasons.

Table 1: Patient demographics.

Variable	Value
Age, Mean (SD)	56.85 (17.46)
≥60 years, n (%)	861 (50.15)
<60 years, n (%)	856 (49.85)
Sex	
Male, n (%)	1148 (66.86)
Female, n (%)	569 (33.14)

The data on anticoagulant amounts, blood processed, and red cells salvaged are outlined in Table 2.

Table 2: Cell saver metrics.

	Volume of anticoagulant used (ml)	Volume of blood processed (ml)	Volume of salvaged red cells (ml)
Minimum	30	63	70
Maximum	11,173	11,633	4,680
Total	1,044,552	2,827,132	934,417
Mean (SD)	608.36 (432.39)	1646.55 (1394.56)	544.22 (479.87)
Median	500	1,308	440

Table 3 below shows the comparison of salvaged red cells by age and sex, with the operations involving males returning more cell salvage (*P*=0.009)

Table 3: Comparison of salvaged cells by age and sex.

Variable	Volume of Salvaged cells	*P*-value
Age		0.466
≥60 years	464999	
<60 years	469418	
Gemder		0.009
Male, n (%)	645506	
Female, n (%)	288911	

Figure 1 below indicates fluctuations in the number of cases over the years, with a peak in 2022. Figure 2 shows the distribution of volumes by year. The distribution of cases by procedure shows that "Other Major Aortic" procedures had the highest number of cases, followed by aortic valve replacement and coronary artery bypass graft (CABG) (Table 4).

Figure 1: The distribution of cases by year.

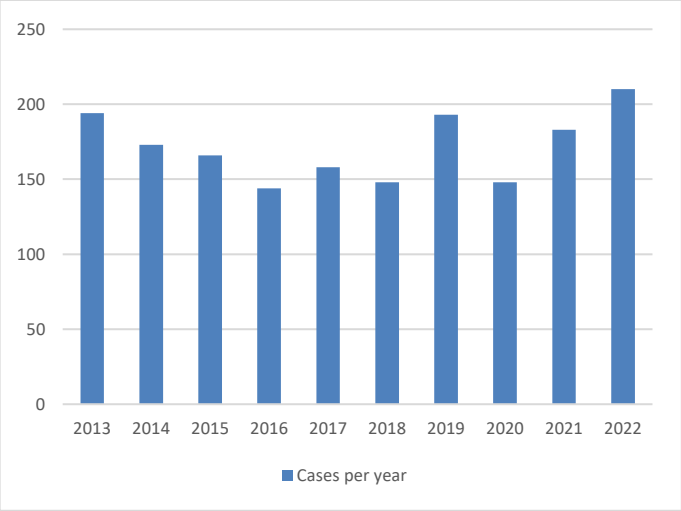
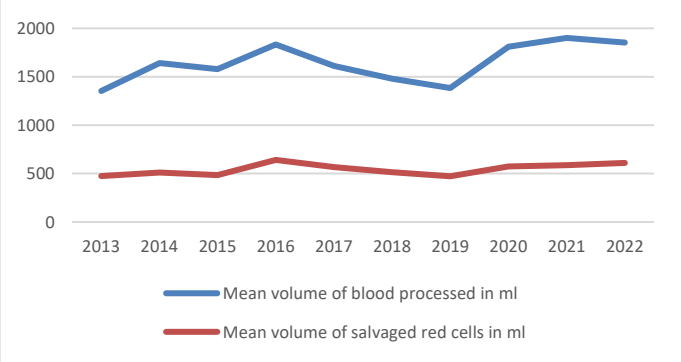


Figure 2: The distribution of volumes by year.



From figure 2 above, statistical comparison between the mean volumes of salvaged cell for the year with the minimum (2019) and maximum (2016) was not significant (2.821).

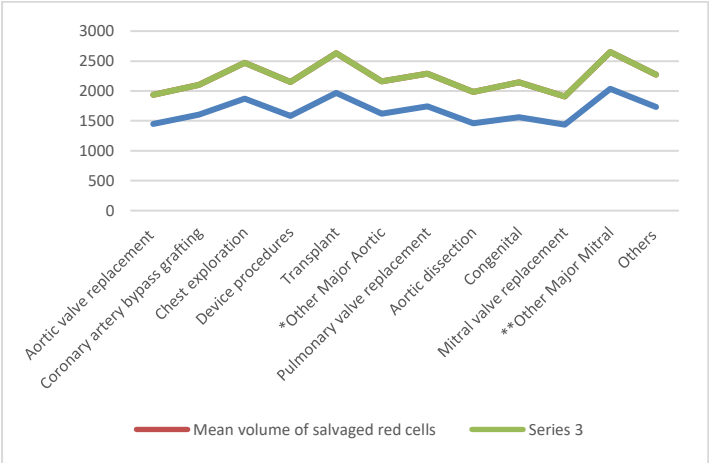
The comparison of cases by volume is presented in the chart below (Figure 3).

Table 4: The distribution of cases by procedure.

Procedure	Number of cases	Percentage
Aortic valve replacement	283	16.48%
Coronary artery bypass grafting	161	9.38%
Chest exploration	136	7.92%
Device procedures	122	7.11%
Transplant	120	6.99%
***Other Major Aortic**	423	24.64%
Pulmonary valve replacement	66	3.84%
Aortic dissection	103	6.0%
Congenital	60	3.49%
Mitral valve replacement	53	3.09%
****Other Major Mitral**	89	5.18%
Others	101	5.88%

* Repair or replacement of any part of the aorta, aortic stenting, Ross procedure, aortic valve repair, aortic valve replacement plus one or more major cardiac procedures
** Mitral valve repair, mitral valve replacement plus one or more major cardiac procedures

Figure 3: The comparison of cases by volume



Discussion

The context of cardiac surgery, with its high use of allogeneic blood products and related dangers, has fueled research into various techniques to lessen reliance on allogeneic transfusions [9]. These techniques include iron supplementation, pharmaceutical therapies, better surgical hemostasis, and cell salvage [10]. Despite the reality that the hazards of blood transfusions have lessened over time, the scarcity and expensive cost of blood necessitates its careful usage [11]. This is exacerbated by the decline in donor availability, which was made worse by the COVID-19 pandemic. Reports show that blood donation rates plummeted by as much as 40% in certain regions due to the cancellation of donation drives and public health concerns [12]. The argument centers on assessing the risks and costs of treatments aimed at reducing transfusion requirements, with cell salvage emerging as a contentious but promising option.

The Society of Thoracic Surgeons and The Society of Cardiovascular Anesthesiologists published a guide for blood transfusion and conservation in cardiac surgery [11]. There are six key variables that increase risk: advanced age, low preoperative red blood cell volume (anemia or small body size), preoperative antiplatelet or antithrombotic medications, re-operative or difficult procedures (such as aortic and congenital procedures), emergency surgeries, and non-cardiac patient comorbidities. Not surprisingly, our audit suggests that major aortic surgeries accounted for the largest use of cell savers in our center.

Numerous studies have investigated the efficacy of cell saver technology in cardiac surgery. In the context of patient blood management, where strategies to reduce dependence on allogeneic blood are increasingly common, autologous blood salvage remains a valuable tool for perioperative blood conservation [1]. Studies have shown that the use of a cell saver reduces exposure to allogeneic blood products and red blood cell transfusions in patients undergoing cardiac surgery [8,13-15]. Even in situations where the use of cell savers was not cost-effective due to the relationship between cell savers and packed cell costs, there are evident benefits for patients, such as a shorter hospital stay [16]. The peculiarities in how this process is executed, such as continuous versus discontinuous processing and variations in washing techniques, can impact patient outcomes. The choice of cell salvage device and the timing of its use during and after surgery are crucial factors that influence the effectiveness of this technique [10].

The cost implications associated with using cell saver technologies in cardiac surgery are multi-faceted. From direct charges, indirect costs, and the possibility for cost savings through lowered transfusion requirements, the financial effects can be viewed from several angles. Using cell savers for intraoperative cell salvage was significantly linked, according to a recent observational analysis, with a reduction of allogeneic RBC transfusions—with a decrease of up to 52% in patients experiencing significant blood loss [15]. Given the costs and risks of transfusing stored blood—which include adverse reactions and outcomes like febrile non-hemolytic transfusion reactions and transfusion-related infections—this decrease is noteworthy [17]. Transfusion reactions can create a major financial burden involving long-term effects of patient morbidity as well as urgent medical expenses. Along with instant savings on blood supplies, this decrease in expenses related to transfusion-related issues yields positive prospects.

Given the robust evidence on the efficacy of cell savers, their use is not without risk. One study highlighted that large volumes of cell-salvaged blood could lead to coagulopathy due to dilution of coagulation factors, activation of fibrinolysis, and residual heparin presence despite the washing process during cell salvage [18]. The authors suggested that a cell salvage volume exceeding a certain threshold could significantly impair fibrin polymerization, potentially necessitating supplementation with fibrinogen concentrate or cryoprecipitate in patient bleeding post-cardiopulmonary bypass.

Safety concerns for cell saver devices include infection risk, transfusion need reduction, and patient outcomes. One of the biggest cell saver device safety concerns is bacterial contamination of reinfused blood. In cardiac surgery patients, red blood cells from cell saver systems can cause bacteremia [19]. This danger is increased with cardiopulmonary bypass (CPB), when blood manipulation can introduce pathogens. Cell savers should be used cautiously in high-risk postoperative cardiac patients due to the unknown source of infections. Although regular antibiotics are used to treat these infections, cell saver systems must be constantly monitored and researched to minimize such repercussions [19]. Preoperative colonization assessment, aseptic techniques, cutting-edge monitoring methods, and sterilization procedures can further reduce these hazards, ensuring that cell saver technology benefits patients without endangering their safety.

In a contrasting study focusing on pediatric cardiac surgical practice, it was highlighted that reinfusion of autologous blood collected by these devices does not raise the risk of hospital-acquired infections or mortality [20]. Given the susceptibility of young patients who are typically undergoing difficult surgical treatments, this result is very important. This reinforces the idea that, when properly controlled, cell saver devices can be safely adopted into the surgical workflow for this demographic. Notwithstanding the benefits, the safety profile of cell saver devices needs constant assessment, especially in view of new data about their use in high-risk surgical operations.

Research on cell salvage has primarily focused on intraoperative interventions and outcomes during the index admission, including the reduction in allogeneic blood transfusions. Meta-analyses and randomized controlled trials have provided insights into the efficacy of cell salvage, with varying conclusions on its impact on transfusion requirements and patient outcomes. While some studies have reported advantages of cell salvage in reducing allogeneic blood product exposure, others have presented conflicting results, underscoring the need for further research and consensus in this area [10].

Jehovah's Witnesses, who typically refuse consent for blood transfusions due to religious reasons, find cell savers to be a viable solution in these challenging situations. The results of a review, which described and compared the cardiac surgery outcomes of Jehovah's Witness patients to non-Jehovah's Witness patients in various case reports, case series, and comparative cohort studies, support this. Many of these studies found no significant differences in the outcomes of the two groups for variables like mortality [21]. However, it is important to emphasize the legal and ethical challenges faced by medical professionals in managing Jehovah's Witness patients undergoing cardiac surgery. The importance of respecting patient autonomy and providing alternative treatments to blood transfusion should be emphasized [20].

The choice of anticoagulant can affect the quality of salvaged red cells and subsequent patient outcomes [22]. Heparin is better than citrate as an anticoagulant during auto-transfusion with cell washing and immediate re-transfusion [23]. This was determined in a study that compared the quality of washed, salvaged red blood cells during total hip replacement surgeries. The median volume salvaged is similar to that in a study, in which results suggested that there was an opportunity to use blood salvage more selectively to improve efficiency, especially in certain surgical procedures.

Accommodating the development of cell saver technology has required continuous study aimed at optimizing the related operations. For instance, a study of the washing solutions applied in cell saver systems found that the solution choice might greatly affect the quality of the obtained red blood cells (RBCs). The findings showed that washing using a bicarbonate-buffered solution not only improved electrolyte balance but also lowered RBC lysis, implying that refining cell saver techniques could help to improve patient outcomes even more [24]. This exposes the need of ongoing development in the approaches related to the usage of cell savers since it directly relates with the effectiveness of blood conservation policies in cardiac surgery.

The operational dynamics of using cell savers have changed; specialized practitioners are now hired to maximize the intraoperative cell salvage procedure. This contrasts with past practices in which anesthesiologists concurrently handling other jobs during surgery generally provided the responsibility of running cell savers. Particularly in high-stakes events involving significant blood loss [25], the creation of specific positions for cell salvage practitioners has proven to strengthen the efficiency and effectiveness of blood recovery procedures. This development in practice emphasizes the need of the human elements influencing the deployment of the technology in clinical environments as well as its inherent nature.

Various factors, including advancements in surgical techniques, changes in patient demographics, and improvements in perioperative care, have contributed to the fluctuations in the number of cases over the years. The impact of the COVID-19

pandemic on the use of cell saver technology in 2020 is evident from the decrease in cases compared to previous and subsequent years. The pandemic caused disruptions in healthcare services, including elective surgeries, which likely contributed to a decrease in cardiac surgery cases utilizing cell saver technology.

Overall, the significant volume of processed blood and red cells salvaged over the 10-year period demonstrates the potential impact of cell saver utilization on reducing the need for external blood products. Furthermore, cases with inadequate processing volume highlight the importance of optimizing cell saver protocols, as properly washing red blood cells reduces postoperative inflammation and transfusion requirements in cardiac surgery [24].

Some insights into the positive influence that this technology has had on patient care are provided by the audit of the use of cell savers in cardiac surgery. This technique emerges as a useful asset since it lessens the requirement for allogeneic blood transfusions, minimizes the amount of blood that is lost during surgery, and has the potential to improve postoperative results. Optimizing the use of cell savers depends on continual research and clinical care to guarantee improved patient outcomes in the high-stakes field of cardiac surgery.

The discussions around the use of cell salvage in cardiac surgery underscore the complexity of balancing the benefits and risks of different blood conservation techniques. Standardizing the approach to cell salvage through well-designed multicenter studies with specified devices is essential in evaluating the long-term advantages and cost-effectiveness of implementing cell savers in a cardiac surgical setting. We can interpret findings in a broader context by integrating findings from relevant literature on cell saver efficacy, blood conservation strategies, and perioperative outcomes in cardiac surgery.

There are certain limitations that must be considered in this study. These constraints are exacerbated by the single-center audit, as the results of a single institution may not be pertinent to larger populations. The study's retrospective approach has the potential to introduce selection bias, and the capacity to draw definitive conclusions is restricted by the absence of comprehensive outcome measurements. Determining a causal relationship between the variables is challenging due to the retrospective nature and single-center context. The absence of causal inference and the potential for selection bias necessitate an interpretation of the connections as hypothesis-generating and preliminary rather than definitive.

Acknowledgments

The authors would like to thank Jessie Villegas, Allan Palmer, and Khubaib Samdani for their help in accessing the data used in the study.

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J Surg Med. 2025;9(11):235-239.
https://doi.org/10.28982/josam.8176

JOSAM

Research article
https://jsurgmed.com/

Journal of Surgery and Medicine

e-ISSN: 2602-2079

Preoperative bathing with chloroxylenol versus non-medicated soap in preventing surgical site infection following inguinal herniorrhaphy

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Ethics Committee Approval
The study was approved by the Health Research Ethics Committee of the University of Benin Teaching Hospital, Nigeria with protocol number: ADM/E 22/A/VOL. VII/148292 on March 24, 2020.
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2025 November 4

Abstract

Background/Aim: Surgical site infections (SSIs) remain prevalent in low- and middle-income countries, exceeding 2% even in clean procedures like elective inguinal herniorrhaphy. While preoperative bathing prevents SSIs, meta-analyses show no advantage of chlorhexidine over non-medicated soap. No studies have compared chloroxylenol soap with non-medicated soap.
Methods: We conducted a prospective randomized study of adults undergoing elective open inguinal herniorrhaphy using the Bassini technique under subarachnoid block. Patients bathed 1 h preoperatively with either chloroxylenol soap (Dettol®) or non-medicated soap (Lux®). We monitored wounds for 30 days using CDC infection criteria and analyzed data using IBM SPSS V 22.0.
Results: The study included 76 patients (93.42% male) with a mean age of 51.72 (18.70) years. The mean operative time was 49.58 (20.06) min. Right-sided hernias comprised 65.79% of cases, with 81.58% being indirect. SSI incidence was 2.63% (one patient per group), showing no significant difference between chloroxylenol and non-medicated soap (P=1.000).
Conclusion: Chloroxylenol soap offers no advantage over non-medicated soap in preventing SSIs after elective inguinal herniorrhaphy.

Keywords: preoperative bathing, chloroxylenol, non-medicated soap, surgical site infection

How to cite: Oghenevwegba A, Richard OU, Ikponmwosa AP, Omorodion I. Preoperative bathing with chloroxylenol versus non-medicated soap in preventing surgical site infection following inguinal herniorrhaphy. J Surg Med. 2025;9(11):235-239.

Introduction

The development of antisepsis by Joseph Lister, followed by the propagation of asepsis by Ernst von Bergman, along with Alexander Fleming's discovery of penicillin in 1929, ushered in the antibiotic era. These advancements significantly reduced the rates of post-operative sepsis resulting from surgical site infections (SSIs) [1, 2].

The rate of SSI is significantly higher in Africa (14.8%) and Nigeria (14.5%) compared to developed nations, such as the United States (1.98%), China (4.5%), and Europe (10%) [3]. In Nigeria, the SSI rate following elective inguinal herniorrhaphy can reach up to 7.79% [4], exceeding the accepted upper limit of 2% for clean surgical procedures [5].

To reduce global SSI rates, the World Health Organization (WHO) recommended preoperative bathing [6]. However, following a meta-analysis of available studies, the WHO found no significant difference between using antiseptic soap versus non-medicated soap for preoperative bathing in the prevention of SSIs.

The researchers identified a gap in the existing literature, noting that chlorhexidine was the only antiseptic agent tested against non-medicated soap. Consequently, they recommended further studies on this topic using antiseptic agents other than chlorhexidine.

This study aimed to compare the efficacy of chloroxylenol-containing soap with non-medicated soap in preventing SSI. It also emphasizes the overall impact of preoperative bathing as a preventive measure against SSI.

Materials and methods

This study was conducted at the Department of Surgery, University of Benin Teaching Hospital, a tertiary health institution in southern Nigeria. The facility serves an estimated population of 3,218,332 and has 870 bed spaces.

This prospective, randomized comparative study involved 76 consenting adult patients, aged 18 years and older, who had unilateral inguinal hernias and underwent elective Bassini inguinal herniorrhaphy. Before surgery, patients received a preoperative bath with either chloroxylenol-containing soap or non-medicated soap. The primary endpoint was the presence or absence of a SSIs 30 days post-surgery.

The exclusion criteria included the following: recurrent inguinal hernias, bilateral inguinal hernias, immunosuppressed patients, the presence of infection near the operation site or at remote sites, patients on systemic antibiotics, and patients with known hypersensitivity to Dettol® and/or Lux® soap.

The study was conducted over 1 year, from April 2020 to March 2021. Patients were consecutively randomized in equal numbers using a simple balloting method.

One group took a preoperative bath with non-medicated soap on the morning of surgery, while the other group used medicated soap containing chloroxylenol (Dettol®, manufactured by Reckitt Benckiser Nigeria Limited). The non-medicated soap used in this study was Lux® (produced by New Home Products Industries Limited for Unilever Nigeria Plc.).

The product information is as follows: Dettol® is packaged as a 65g bar soap. Each bar contains the following ingredients: Soap Base, talc, glycerin, sodium C14-C16 olefin sulfonate, water, fragrance, color, silicon emulsion, and chloroxylenol at 0.3% w/w. It also has a total fatty matter of not less than 64% w/w upon packaging. The batch number is ADO-053W. The date of manufacture is 20th April 2019, and the expiry date is April 2023.

The Lux® bar soap is packaged as a 65g bar and comprises several ingredients. These include Soap Base, Aqua, Glycerin, Parfum, *Rosa gallica* flower extract, *Jasminum officinale* flower extract, *Prunus amygdalus* oil, *Cymbopogon martini* oil, PEG-40 hydrogenated castor oil, *Mentha arvensis* leaf extract, Titanium dioxide, Citric acid, Alpha-isomethyl ionone, Methylpropional, and Potassium sorbate. The soap has a total fatty matter content of 67% w/w upon packaging. The batch number for this product is 154N2. It was manufactured on June 3, 2019, and has an expiry date of June 3, 2023.

Both groups received clean theatre apparel before being transferred to the theatre. After the bath, no cosmetics were applied. Additionally, none of the patients received prophylactic antibiotics.

All patients underwent evaluation, with age, gender, and hernia site recorded. Preoperative investigations included a full blood count, urinalysis, random blood sugar, and serum electrolytes, urea, and creatinine. Patients over 40 years old also received a chest x-ray and an electrocardiogram.

Each patient was admitted the day before surgery for a routine preoperative anesthetic review, during which informed consent was obtained. Patients were assigned to groups based on the serial numbers in a table of random numbers. The research assistant distributed the appropriate soap to each patient. The type of soap allocated to each patient was concealed from the researcher until after all data had been collected.

On the morning of surgery, trained assistants provided patients with instructions on the bathing procedure. Patients then took a shower within 1 h before surgery using the allocated soap and polyester sponge. This process included 15 min of bathing, with the affected groin cleansed for 5 min before a full body shower. A male or female research assistant, matched to the patient's sex, timed and supervised the bath. Separate shower rooms were available for patients. If shaving was necessary, the research assistant performed it with a shaving stick before the bath. There were no visible injuries reported after shaving. The researcher supplied both the soap and polyester sponges.

Surgeries were performed under subarachnoid block, and no preoperative antibiotics were administered. Skin preparation adhered to the protocol of applying Savlon twice, allowing it to dry, and then applying povidone-iodine. This was followed by isolation using the four-drape technique.

A transverse groin skin crease incision was made 2.5 cm above the medial two-thirds of the inguinal ligament. The incision was developed through the subcutaneous fat, and the external oblique aponeurosis was incised obliquely to the superficial ring to access the inguinal canal. Hemostasis was achieved with monopolar diathermy. In males, the spermatic cord was elevated, and the hernia sac was dissected off it. In females, the sac was dissected off the round ligament. High ligation of the hernia sac was performed using Vicryl 1 suture, and the sac was excised. The posterior wall repair for all patients employed the modified

Bassini technique. This technique involved approximating the conjoint tendon to the inguinal ligament using interrupted polypropylene 1 sutures. The first suture was placed through the inguinal ligament near its attachment to the symphysis pubis, then through the conjoint tendon on the opposite side, and tied without tension. These interrupted polypropylene sutures were continued from the medial end of the inguinal canal laterally, ensuring the spermatic cord was not included in the sutures and the internal ring was not made too tight. The spermatic cord was returned to the inguinal canal, and the external oblique aponeurosis was repaired over it with continuous Vicryl 1 suture. The subcutaneous layer was closed with interrupted Vicryl 2-0 sutures, and the skin was closed with Vicryl 2-0 sutures in a continuous subcuticular fashion. The wound was then cleaned with Savlon, dried, cleaned with povidone-iodine, and dressed. No antibiotics were administered postoperatively. Patients were transferred to the ward for recovery from anesthesia and observation for early complications. They were discharged the day after surgery and were seen on the 4th, 7th, 14th, and 30th day post-operation for wound inspection. These inspections were conducted by senior registrars in general surgery, who were blinded to the soap used by the patient and not involved in the surgical procedure. They assessed for signs of SSI such as fever, increasing pain and swelling at the operation site, erythema, tenderness, wound edema, serous or purulent discharge, or wound dehiscence.

Patients were instructed to contact the researcher between the scheduled visits if they experienced any wound complications, including pain, erythema, swelling, or serous or purulent discharge.

When an infection was suspected, the researcher collected wound swabs and promptly delivered them to the laboratory for microscopy, culture, and sensitivity tests. Wound care was prescribed as necessary. Identified organisms were documented.

SSIs was defined according to the CDC criteria [7]. Superficial incisional SSI is characterized by at least one of the following: purulent drainage from the superficial incision (involving only skin and subcutaneous tissue); organisms identified from an aseptically obtained specimen from the wound; or an incision deliberately opened by the surgeon for drainage, accompanied by any of the following symptoms: localized pain or tenderness, swelling, erythema, or heat.

Deep incisional SSI is characterized by at least one of the following criteria: purulent discharge from the deep incision, involving fascia and muscles; spontaneous dehiscence of the deep incision, or when it is deliberately opened or aspirated by the surgeon to drain pus; identification of organisms from the deep space, accompanied by the patient experiencing any of the following symptoms: fever (temperature greater than 38°C), localized pain, or tenderness.

Organ space SSI is indicated by at least one of the following criteria: organisms identified in the organ space; an abscess involving the organ space detected by histopathologic exam or imaging.

Statistical analysis

Data collected during the pre- and post-operative assessments were documented using a predesigned form. We analyzed the data with the IBM Corporation Statistical Package for the Social Sciences (SPSS) Statistics for Windows, Version 22.0, Armonk, New York, United States of America. We compared infection rates in both groups using the chi-square test, with the significance level (p) set at 0.05. Results were presented in the form of tables, graphs, and charts.

Approval for this study was obtained from the Ethics Committee of the University of Benin Teaching Hospital in March 2020, under Protocol Number: ADM/E22/A/VOL, VII/148292.

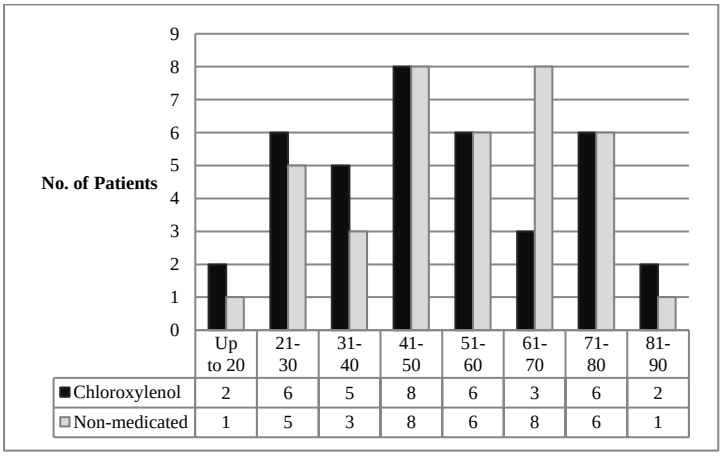
Patients were counseled on the nature of the study, and written informed consent was obtained prior to recruitment. Participation was voluntary, confidential, and incurred no additional financial cost to the participants.

Results

Seventy-six patients with uncomplicated inguinal hernias were recruited for this study. They were randomized into two groups of 38 patients each: one group received a preoperative bath with chloroxylenol-containing soap (Dettol®), while the other used non-medicated soap (Lux®). All patients completed the mandatory 30-day follow-up in the clinic.

Patient characteristics, including mean age distribution (Figure 1) and gender distribution (Table 1), did not have statistically significant effects on either group that might have influenced the outcome differently (P>0.05).

Figure 1: Age distribution. (T=0.340, P=0.735).



Most (65.79%) of the hernias occurred on the right side. However, the distribution between the groups was not statistically significant (P=0.629) (Table 2). Indirect inguinal hernias constituted 81.58 percent of the study population (Figure 2). In comparison, 92.11 percent of participants bathed with non-medicated soap, whereas 71.05 percent used chloroxylenol-containing soap. This disparity was statistically significant (P=0.0179) (Figure 3).

Table 1: Gender distribution.

	Total n=76	Chloroxylenol n=38	Non- medicated n=38	Stat test	*P*-value
Gender					
Male	71 (93.42%)	35 (92.11%)	36 (94.74%)	χ2=0.214	0.644
Female	5 (6.58%)	3 (7.89%)	2 (5.26%)		

Table 2: Hernia location.

	Total n=76	Chloroxylenol n=38	Non- medicated n=38	Stat test	*P*-value
Side					
Right	50 (65.79%)	26 (68.42%)	24 (63.16%)	χ2=0.234	0.629
Left	26 (34.21%)	12 (31.58%)	14 (36.84)		

For indirect and direct inguinal herniorrhaphy, the difference in the mean duration of surgery was not statistically significant (P=0.615) (Table 3). Additionally, when comparing

both study arms, the mean duration of surgery was longer in the chloroxylenol group; however, this difference was also not statistically significant ($P>0.05$) (Table 4).

Two patients developed SSI, one in each group, resulting in identical infection rates of 2.63%. The SSIs were observed on the seventh day after surgery, evidenced by a seropurulent discharge. Wound cultures identified the presence of *Staphylococcus epidermidis*. There was no statistically Significant Difference In The SSI Rates Between The Two Groups ($P=1.000$; Table 5).

Figure 2: Type of hernia.

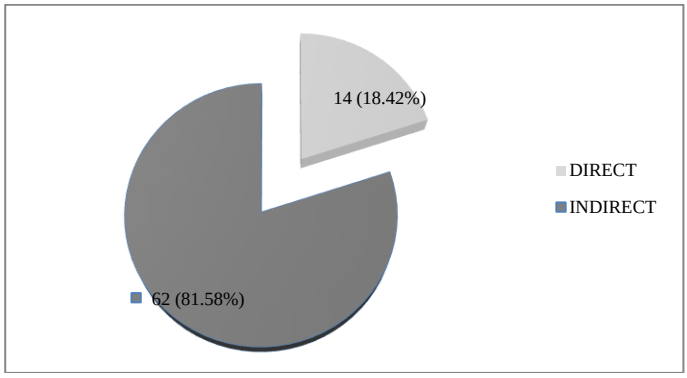


Figure 3: Type of hernia per group ($\chi 2=5.603$).

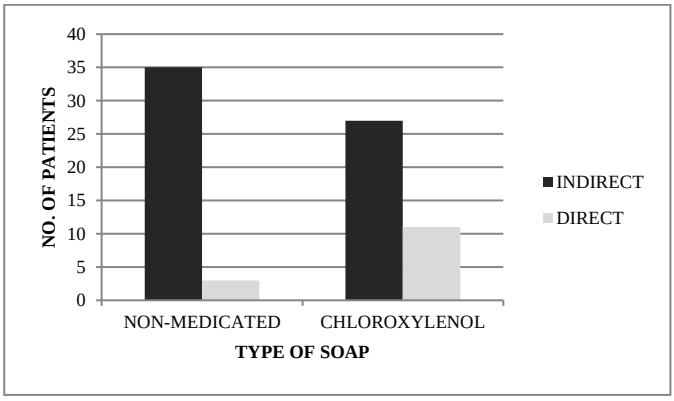


Table 3: Duration of surgery in minutes (direct vs indirect hernias) ($P=0.615$)

	Total n=76	Direct n=14	Indirect n=62	Stat test	*P*-value
Range	30-110	30-110	30-106		
Mean (SD)	49.58 (20.06)	51.86 (25.96)	48.90 (18.20)	t=0.505	0.615

Table 4: Duration of surgery in minutes (chloroxylenol vs non-medicated).

	Total n=76	Chloroxylenol n=38	Non-medicated n=38	Stat test	*P*-value
Range	30-110	30-105	30-110		
Mean (SD)	49.58 (20.06)	50.79 (19.57)	48.11 (19.98)	t=0.590	0.557

Table 5: Surgical site infection (chloroxylenol vs non-medicated).

	Total	Chloroxylenol	Non-medicated	Stat test	*P*-value
No. of hernias	76	38	38		
No of infections	2	1	1		
SSI rate	2.63%	2.63%	2.63%	$\chi 2=0$	1.000

Discussion

This study recruited 76 patients over 1 year, and all participants completed the 30-day follow-up. There were two infections, resulting in an overall SSIs rate of 2.63%. The infection rates were identical in both the chloroxylenol and non-medicated soap groups.

Both groups were similar in age, gender distribution, hernia characteristics, and the duration of surgery. However, there was a statistically significant difference between the groups concerning the distribution of direct and indirect hernias. Aside from the anatomical differences between direct and indirect hernias, the preparation and surgical procedures were the same for both types, and there was no significant difference in the duration of surgery.

In this study, the age distribution of inguinal hernias peaked in the fifth decade of life. This finding aligns with Malviya et al. [8], who reported a peak age range in the 5th to 6th decades, and Awe et al. [9], who found peaks in the 4th to 5th decades. Ashindointiang et al. [10] observed a peak age in the 7th decade among an all-male population; notably, one-third of their patients were over 60 years old, which corresponds with this study, where 26 of the 76 subjects were above 60. These results differ from Burchart et al.'s [11] study in Denmark, which found a peak incidence in the 8th decade. The variation might be attributed to Denmark's higher life expectancy compared to developing countries like Nigeria [12,13] and an older population experiencing progressive muscle atrophy and an increased risk of hernia formation [11].

The majority of patients in this study were male, which aligns with the findings of Malviya et al. [8], where 94.6% of the subjects were also male. This pattern is likely due to the anatomical passage of the spermatic cord from the abdomen through the inguinal canal to the scrotum during intrauterine development. This process results in a wider deep ring and inguinal canal in males, making them more susceptible to inguinal hernias [14]. Additionally, males are often more involved in strenuous exercises and heavy lifting, activities that increase intra-abdominal pressure and contribute to the development of hernias [15].

This study identified a predominance of right inguinal hernias. Balamaddaiah et al. [15] reported similar findings. The occurrence could be attributed to the slower descent of the right testicle into the scrotum and the persistence of the processus vaginalis on the right side in males [8]. Additionally, a history of open appendectomy may contribute, as the procedure can potentially injure the iliohypogastric nerve, leading to weakness in the posterior wall of the inguinal canal [16].

The indirect type was more common than direct hernias. This is attributable to the existence of the deep ring (and persistent processus vaginalis) which is a preexisting defect through which inguinal hernias can occur [14].

Two SSIs were recorded during this study, resulting in an SSI rate of 2.63%. This rate slightly exceeds the maximum expected rate after clean surgery, which is 2% [5], yet it is lower than rates reported by Ugwu-Olisa et al. [17] at 3.9%, Ramyil et al. [4] at 7.79%, and Kumar et al. [18] at 10%. The lower incidence observed in this study may be attributed to the exclusion of patients at high risk of infection, who would have required prophylactic antibiotics, potentially affecting the uniformity of the sample.

Both groups experienced one infection each, resulting in an infection rate of 2.63%. Therefore, chloroxylenol-containing soap demonstrated no superiority over non-medicated soap in preventing SSIs following open inguinal herniorrhaphy.

Both infections were identified during a clinic visit on the 7th post-operative day, a timeframe typical for the emergence of SSIs symptoms [19].

Both patients exhibited seropurulent discharge from the operation site, leading to a classification of superficial incisional

SSIs. Wound swabs were taken and cultured, and both cases yielded *Staphylococcus epidermidis*. The isolates were multidrug-resistant, showing sensitivity only to Azithromycin and Gentamicin. This finding contrasts with Ehiaghe et al. [20], who identified Pseudomonas aeruginosa as the predominant bacterial isolate in 181 swabs from infected surgical wounds at the University of Benin Teaching Hospital. In that study, *S. epidermidis* was not isolated from any specimens.

S. epidermidis is a coagulase-negative, Gram-positive organism. It, together with *S. haemolyticus* and *S. saprophyticus*, represents the most common species among coagulase-negative staphylococci and forms part of the normal flora, particularly around the head, nares, and axilla [21]. This organism exhibits higher methicillin resistance (75–90%) compared to *S. aureus* (40–60%). Consequently, it has emerged as a significant cause of hospital-associated infections, especially in the context of medical devices [22].

Both patients experienced drainage of effluent through existing defects in their wounds, which were managed with wound dressings applied every other day. The wounds were cleaned with saline and dressed with sterile gauze in an outpatient setting. By their next clinic visit, 14 days post-operation, the infections had resolved. These patients with SSI incurred additional costs due to the need for dressing packs, normal saline, and transportation to and from the hospital every other day during the wound dressing period.

In this study, preoperative bathing with chloroxylenol-containing soap showed no difference in the incidence of SSIs compared to non-medicated soap; both groups experienced an SSI rate of 2.63%. This incidence is lower than those reported in other studies, which range from 3.9% to 10% [4,17,18]. However, these other studies did not specify whether preoperative bathing was mandatory for all patients.

Limitations

The inability to directly observe the baths, due to privacy and decency concerns, may have impacted full compliance with the bathing modalities. Additionally, the small patient sample size may limit the generalizability of our findings. To increase the acceptability of these research results, conducting a larger, multi-center study could help reduce bias.

Conclusion

The rate of SSIs was similar in both groups. However, the non-medicated soap is both more cost-effective and equally effective as chloroxylenol-containing soap in preventing SSIs after inguinal herniorrhaphy. Therefore, its routine use should be considered, particularly in low- to medium-income countries.

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J Surg Med. 2025;9(11):240-244.
https://doi.org/10.28982/josam.8456

JOSAM

Research article
https://jsurgmed.com/

Journal of Surgery and Medicine

e-ISSN: 2602-2079

Computed tomography evaluation of elongated styloid process and calcified stylohyoid ligament: Revisiting Eagle's syndrome

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Ethics Committee Approval
The study was approved by Ankara Yıldırım Beyazıt University, Yenimahalle Training and Research Hospital Non-Interventional Scientific Research Ethics Committee, decision number E-2025-31, dated October 30, 2025.
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2025 November 27

Abstract

Background/Aim: Eagle's syndrome (ES) presents with a wide range of symptoms resulting from the impingement of nerves and/or compression of vessels in the neck by an elongated styloid process and calcified stylohyoid ligament. Although the literature includes numerous case reports on ES, large patient series studies are limited. This study aims to provide a comprehensive analysis of ES, evaluate its consistency with existing literature, and report findings from 88 patients, representing one of the largest series to date conducted at a high-volume center specializing in head imaging.
Methods: A retrospective analysis was conducted on 8,509 patients who underwent computed tomography (CT) for various indications between 2019 and 2023. A total of 88 patients were diagnosed with ES. For each patient, preliminary diagnosis and gender were recorded.
Results: Out of 8,509 patients evaluated, 88 (1.0%) were diagnosed with ES. Of the 88 confirmed ES cases, 47 (53.4%) were female and 41 (46.6%) were male. It was determined that 3 of the 88 patients (3.4%) diagnosed with ES had a preliminary diagnosis of ES, while 96.6% did not have a preliminary diagnosis.
Conclusion: Establishing a strong preliminary diagnosis of ES, rather than identifying it incidentally on imaging, depends on a detailed knowledge of regional anatomy and the ability to correlate clinical symptoms with underlying anatomical structures. Of the 88 patients diagnosed with ES, 3 (3.4%) had a preliminary diagnosis—all of whom were women—while the remaining 96.6% did not. Our findings highlight a marked discrepancy between clinical suspicion and radiological diagnosis of ES. This gap underscores the importance of incorporating objective imaging into routine evaluation to improve diagnostic accuracy and prevent misdiagnosis.

Keywords: stylocarotid syndrome, styloid process, internal carotid artery, Eagle's syndrome, carotid artery syndrome

How to cite: Akkaşoğlu Taş S, Çetin H, Çalışkan S. Computed tomography evaluation of elongated styloid process and calcified stylohyoid ligament: Revisiting Eagle's syndrome. J Surg Med. 2025;9(11):240-244.

Introduction

Eagle first described what is now known as Eagle syndrome (ES) in 1937, based on a patient he had observed over several years. The patient presented with persistent throat and ear pain following a tonsillectomy and was initially considered neurotic due to the lack of visible pathology. In 1935, Eagle palpated a firm and tender structure in the left tonsillar fossa, which reproduced the patient's symptoms. This finding led to the identification of an elongated styloid process as the underlying cause of the clinical presentation [1, 2].

The symptoms associated with Eagle's syndrome are primarily attributed to two pathophysiological mechanisms: impingement or irritation on nearby nerves in the neck, and compression of adjacent carotid arterial branches or their tributaries [1, 3].

Eagle noted that typical cases of the syndrome often involve neuralgic symptoms due to irritation of the sensory and motor fibers of the glossopharyngeal (IX) nerve, and less commonly the trigeminal (V), facial (VII), and vagus (X) nerves. Patients may experience altered taste, pharyngeal or esophageal muscle spasms, and pain during swallowing. Symptoms frequently arise after tonsillectomy, likely due to scar tissue irritating nearby nerve endings. The typical presentation of the syndrome occurs when the elongated styloid process is directed anteriorly or medially, which is its most common orientation. Surgical shortening of the elongated styloid process often relieves these symptoms.

In 1946, Eagle described a variant of ES called carotid artery syndrome (or stylocarotid syndrome), in which pain follows the pathway of the internal or external carotid artery. This condition was based on a case where an elongated and curved styloid process compressed the external carotid artery, leading to chronic head and neck pain. Some patients may also experience tinnitus, possibly due to vibrations transmitted through bone, even though the cochlea is supplied by the basilar artery. In such cases, the internal carotid artery may be abnormally superficial and tender due to displacement by the styloid process. This can lead to diagnostic confusion, as the prominent artery might be mistaken for an enlarged cervical lymph node. Repeated self-palpation can worsen the pain, which is thought to result from irritation of the sympathetic nerve fibers in the arterial wall [1, 4].

The literature is abundant in case reports and small case series on ES, but comprehensive studies remain limited [5-14]. Additionally, there is inconsistency regarding whether the syndrome is primarily characterized by unilateral or bilateral elongation of the styloid process. This variability largely stems from differing definitions and diagnostic criteria applied across studies. A review of the literature reveals considerable confusion among researchers concerning the laterality and incidence of ES, as most reports focus on either its vascular or neurological clinical presentations rather than the anatomical basis of the syndrome as a whole.

The present study addresses this gap by providing a large-scale, anatomy-based assessment of Eagle syndrome confirmed by multidetector computed tomography (MDCT). It is the first to evaluate the consistency between preliminary clinical diagnosis and radiological confirmation, offering a more objective understanding of the syndrome's true prevalence and laterality.

Materials and methods

This retrospective cross-sectional study evaluated the prevalence and diagnostic concordance of ES using MDCT at Ankara Bilkent City Hospital between January 1, 2019, and December 31, 2023.

Ethical approval was obtained from the Yenimahalle Research and Training Hospital Ethics Committee (approval number: E-2025-31).

Patients undergoing head and neck MDCT were considered. Patients were excluded if they met any of these criteria: age under 18 years, fractures involving the head or neck, prior head or neck surgery, poor-quality or incomplete MDCT images, or incomplete clinical records. After exclusions, 8,509 patients were included in the analysis.

The preliminary diagnosis of ES was recorded based on the referring physician's notes documented in the electronic patient charts prior to the MDCT.

The primary outcome was ES, defined as a styloid process >3 cm with calcified stylohyoid ligaments. Secondary outcomes included concordance between preliminary clinical diagnosis and radiological confirmation. Demographic data (age, sex) were collected from hospital records. All MDCT scans were systematically reviewed using standardized anatomical criteria.

Potential bias from retrospective data and incomplete clinical records was addressed by standardizing imaging review and data extraction methods.

The final cohort included 8,509 patients, of whom 88 (1.0%) were diagnosed with bilateral ES.

Statistical analysis

Descriptive statistics for age were provided as mean (SD), while for discrete data, the number and percentage values were given. The Independent Samples t-test was used to compare the ages of women and men. The McNemar test was used to compare the ES rates of preliminary diagnosis and CT diagnosis. Fisher's exact test was used to compare the rates of preliminary diagnoses between women and men. Statistical analyses were performed using the Statistical Package for the Social Sciences (version 20.0; SPSS Inc., Chicago, IL, USA). A p-value of less than 0.05 was considered statistically significant.

Results

Out of 8,509 patients evaluated, 88 (1.0%) were diagnosed with bilateral ES. Of the 88 confirmed ES cases, 47 (53.4%) were female and 41 (46.6%) were male. The average age of patients was 51.54 (13.98) years, with a minimum age of 25 and a maximum age of 76. There was no statistically significant difference in age between female and male patients with ES (P=0.137) (Table 1). Of the 88 patients diagnosed with ES, 3 (3.4%) had a preliminary diagnosis—all of whom were women—while the remaining 96.6% did not have a preliminary diagnosis. Preliminary diagnosis rates were compared between female and male patients with ES, and no statistically significant difference was found (P=0.245) (Table 2). Concordance between preliminary diagnosis and CT confirmed ES was assessed (P=0.016) (Table 3).

Computed tomography scans showed bilateral styloid processes were more than 3 cm long and calcified stylohyoid ligaments (Figure 1–4).

Table 1: Comparison of age between women and men with ES

	Mean (SD)	*P*-value
Female	49.46 (13.18)	0.137
Male	53.92 (14.64)	

SD: Standard Deviation

Table 2: Comparison of preliminary diagnosis rates between women and men with ES

Preliminary diagnosis	Female n(%)	Male n(%)	*P*-value
No	44 (93.6)	41 (100)	0.245
Yes	3 (6.4)	0 (0.0)	

n: number

Table 3: Comparison of ES rates between preliminary diagnosis and CT diagnosis

Preliminary diagnosis (ES)	Post-CT diagnosis (ES) No n(%)	Post-CT diagnosis (ES) Yes n(%)	*P*-value
No	81 (100)	0 (0.0)	0.016
Yes	7 (77.8)	2 (22.2)	

McNemar test

Figure 1: Coronal computed tomography (CT) scan shows bilateral elongated styloid processes (red arrows) and calcified stylohyoid ligament (yellow arrows).

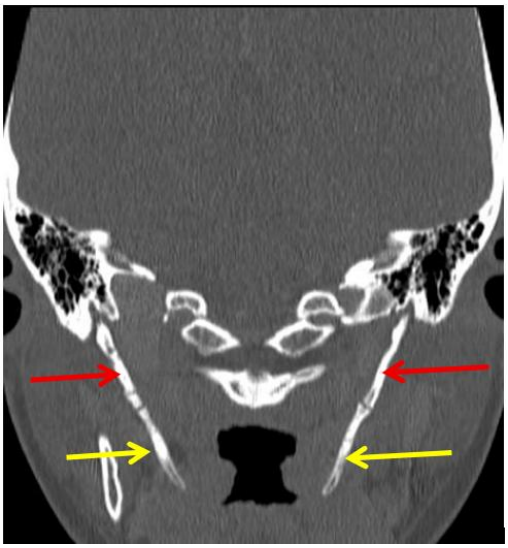


Figure 2A: Axial section, the stylohyoid ligaments are calcified (red arrows) and indented laterally on both palatine tonsils (blue arrows).

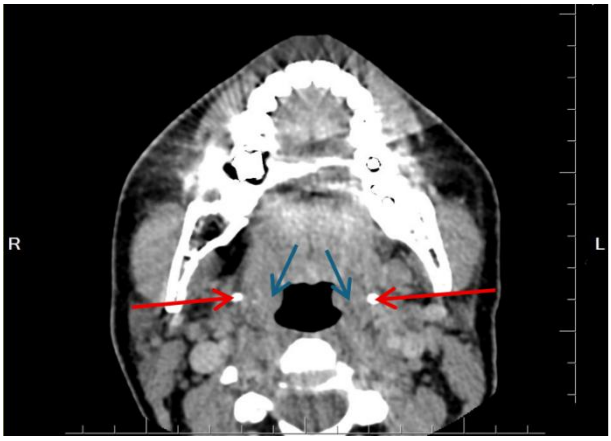


Figure 2B: Axial section, elongated styloid process (red arrows).

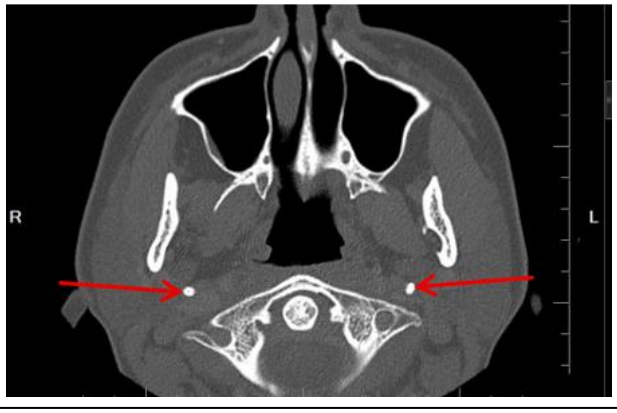


Figure 3: Parasagittal section, elongated styloid process (red arrow) and stylohyoid ligament calcification (yellow arrow).

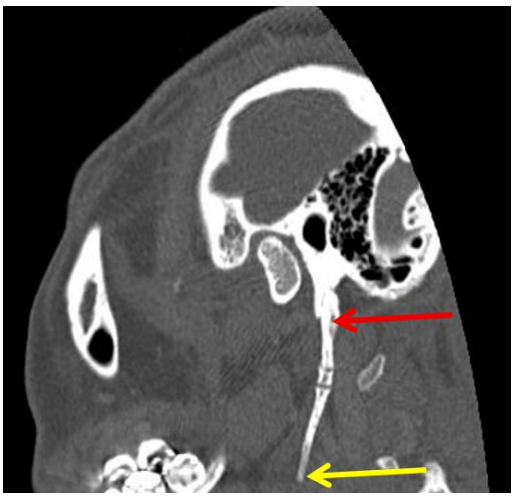
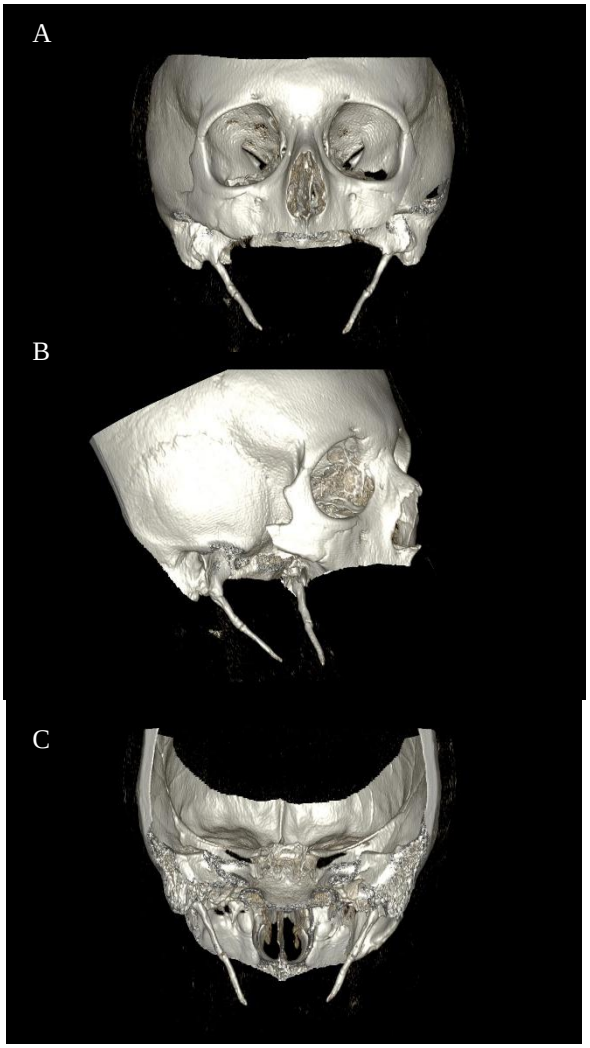


Figure 4A, B, C: Three dimensional (3D) computed tomography demonstrated bilateral elongated styloid processes and calcified stylohyoid ligaments. **A:** anterior view, **B:** oblique view, **C:** posterior view



Discussion

Eagle described the syndrome in patients who had previously undergone tonsillectomy, which is characterized by the elongation of the styloid processes and the presence of symptoms attributable to this anatomical variation. Eagle linked the symptoms to postoperative fibrosis between the tonsillar fossa and styloid process, which compresses the trigeminal, facial, glossopharyngeal, or vagus nerves [1, 2].

There is an ongoing discrepancy between the original Eagle's literature and the current literature regarding the definition of ES. While a substantial number of published articles describe ES as symptomatic, many current literature sources assert that the condition should be defined specifically as symptomatic and/or asymptomatic.

Literature contains numerous reports of ES cases that are incidentally diagnosed through imaging with nonspecific clinical presentation [15, 17-19]. However, a closer analysis of these cases reveals that the patients are not truly asymptomatic; rather, they exhibit nonspecific symptoms that, upon detailed evaluation, can be anatomically attributed to ES [3, 5, 15-19]. This inconsistency may lead to confusion in both diagnosis and reporting, highlighting the need for a more unified and standardized definition.

This study presents 88 cases of ES, each involving bilateral elongation of the styloid processes accompanied by symptoms that are anatomically consistent with this structural anatomy. From this perspective, we believe that our study provides a precise definition of the syndrome and that the results derived from this framework are more scientific and objective compared to previous studies.

Several studies in the literature report that the prevalence of an elongated styloid process is approximately 4–7%, with 4–10% of these cases being symptomatic [3, 5, 20, 21]. In the study by Pagano et al. [5], only cases of vascular Eagle syndrome were reviewed. Among the 31 articles included, one reported two cases, another five cases, and the remaining articles presented a single case each; the authors also contributed a case from their own experience. Unlike that study, which focused exclusively on the vascular subtype, the present study provides comprehensive data on the overall prevalence of ES, including both vascular and neurological forms.

Searle et al. [15] described ES as typically unilateral and less commonly bilateral, estimating its incidence at 4–8 per 10,000 individuals. In the case report by Dabrowski et al. [16], unilateral ES was described as relatively rare, while bilateral ES was characterized as "exponentially more rare" and noted to have been mentioned only a few times in the literature. Bilateral ES was observed in 1.0% (88/8509) of our cases. Although earlier studies have reported bilateral involvement as extremely rare—often rarer than unilateral cases—our bilateral rate exceeded the unilateral rates reported in aforementioned studies, underscoring the strength and distinct contribution of our study. Given the significantly larger sample size and inclusion of all subtypes but only bilateral cases, the incidence reported in our study may offer a more accurate estimate of the true prevalence of bilateral ES in the general population.

Moreover, this study contributes to the literature by highlighting, for the first time, the concordance between preliminary clinical suspicion of ES and radiological confirmation using MDCT. Among 8,509 patients, only 9 were initially suspected to have ES based on clinical evaluation; however, 88 patients were ultimately diagnosed with the condition through imaging. Of the 9 patients with a preliminary diagnosis, only 3 (33.3%) were confirmed to have ES radiologically. Thus, the rate of true-positive preliminary diagnoses was just 0.035%, while the actual incidence of ES in the study population was 1.0%.

This significant discrepancy between clinical suspicion and confirmed diagnosis underscores the importance of improving clinical recognition of ES. Given the syndrome's wide range of symptoms—often involving cranial nerves (V, VII, IX, and X) and major vascular structures such as the internal and external carotid arteries—physicians should be aware of the varied clinical presentations. A thorough understanding of the anatomical basis and pathophysiology of ES is essential for improving diagnostic accuracy and ensuring that more cases are identified correctly at the preliminary stage. Moreover, these findings suggest that MDCT is more reliable than clinical suspicion alone for the accurate diagnosis of ES. Nevertheless, as our results are based on retrospective data, they should be interpreted with caution. To the best of our knowledge, this is the first study to draw attention to this diagnostic discrepancy between clinical suspicion and radiological confirmation. We aimed to highlight this issue and encourage further research on the subject. To substantiate our observations and determine the true diagnostic value of MDCT compared with clinical evaluation, well-designed prospective studies with larger sample sizes are warranted.

Conclusion

To establish a common language in the evaluation of ES, it is essential to first reach a consensus on its definition. Without this fundamental agreement, data regarding incidence, gender distribution, and diagnostic criteria remain inconsistent and lack scientific objectivity. The current literature demonstrates considerable variability on this point, further complicating efforts to standardize diagnosis and compare findings across studies. The present study, in our view, fills a gap on this discrepancy with the largest case series analyzed to date.

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J Surg Med. 2025;9(11):245-250.
https://doi.org/10.28982/josam.8219

JOSAM

Review
https://jsurgmed.com/

Journal of Surgery and Medicine

e-ISSN: 2602-2079

Sleep quality and its association with recovery in patients undergoing total knee arthroplasty: A systematic review

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Ethics Committee Approval
Ethical approval was not required, as the data was sourced from an open-access archive. This study does not contain identifying information of the patients. Informed consent was not required due to design of the study.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2025 November 5

Abstract

Background/Aim: Sleep disturbances are a prevalent but often overlooked issue among patients undergoing total knee arthroplasty (TKA). These disruptions significantly contribute to increased pain, delayed functional recovery, and reduced quality of life. This systematic review examines the association between sleep quality and postoperative recovery outcomes after TKA.

Methods: The review utilized five databases: PubMed, Embase, Ovid/MEDLINE, CINAHL, and Scopus. We identified studies that evaluated sleep quality and recovery outcomes in adult TKA patients. Eligible studies used validated tools such as the Pittsburgh Sleep Quality Index (PSQI), Insomnia Severity Index (ISI), and actigraphy to examine recovery metrics, including pain, mobility, and overall recovery trajectories. A narrative synthesis was conducted to identify patterns and variations across the included studies.

Results: Seven studies, involving a total of 902 patients, were included in this review. Poor sleep quality is consistently correlated with adverse recovery outcomes, such as higher pain levels, slower functional recovery, and diminished quality of life. Quantitative data underscored the association between elevated PSQI scores and delayed recovery metrics. Patients with higher PSQI scores reported elevated pain levels (VAS: 3.8 vs. 1.6) and poorer functional outcomes, as indicated by significantly higher WOMAC-Physical Function scores several weeks after TKA compared to groups with less prominent insomnia ($P<0.05$).

Conclusion: Interventions targeting sleep disturbances, such as behavioral therapies, showed promising benefits. However, methodological variability limited the generalizability of findings. This review emphasizes the critical importance of sleep quality as a modifiable factor in optimizing recovery after TKA. Integrating sleep assessments and targeted interventions, such as cognitive-behavioral therapy for insomnia (CBT-I), into perioperative care can significantly enhance recovery trajectories and patient outcomes. Future research should prioritize standardizing methodologies and investigating the effectiveness of sleep-focused strategies across diverse patient populations.

Keywords: total knee arthroplasty, sleep quality, recovery, Pittsburgh Sleep Quality Index, actigraphy

How to cite: Vasquez Jr. VM, Ngatuvai M, Sohail N, Joshua Hansen J, Rainey J, Purcell R. Sleep quality and its association with recovery in patients undergoing total knee arthroplasty: A systematic review. J Surg Med. 2025;9(11):245-250.

Introduction

Total knee arthroplasty (TKA) ranks among the most frequently performed orthopedic procedures, primarily aimed at alleviating pain and restoring mobility in individuals with advanced knee osteoarthritis [1,2]. Globally, over a million TKA procedures are conducted annually [3], with this figure expected to rise due to aging populations and increasing rates of osteoarthritis [4]. Success in TKA is conventionally assessed through improvements in pain relief, range of motion, and functional recovery. However, these metrics often neglect other critical factors influencing outcomes, such as sleep quality.

Sleep disturbances are a common yet underrecognized issue in patients undergoing TKA. Poor sleep quality is associated with slower tissue healing, heightened pain sensitivity, and delays in rehabilitation [5,6]. Contributing factors include postoperative pain, restricted mobility, anxiety, and the disruptive nature of hospital environments. Although the relationship between sleep and recovery has been studied in other surgical contexts, its specific impact on TKA recovery remains insufficiently explored [7,8].

Recent research employing validated tools such as the Pittsburgh Sleep Quality Index (PSQI) and Insomnia Severity Index (ISI) has initiated efforts to map the connection between sleep quality and recovery outcomes [9]. Studies demonstrate that sleep quality is linked not only with pain levels but also as a modifiable factor that can significantly enhance physical rehabilitation and overall quality of life [10,11]. Furthermore, interventions like cognitive-behavioral therapy and pharmacological treatments show promise in addressing sleep disturbances and improving outcomes in comparable patient groups [12,13].

Research in this area is expanding, yet there is still a need for a comprehensive review to synthesize current literature, identify emerging knowledge gaps, and offer up-to-date, evidence-based recommendations for clinical practice. This systematic review aims to assess existing evidence on the role of sleep quality in postoperative recovery for patients undergoing TKA. By analyzing the available literature, we intend to evaluate the significance of incorporating sleep-focused interventions into perioperative care plans to optimize recovery outcomes.

Objectives

This systematic review aims to investigate the associations between sleep quality and postoperative pain, functional recovery, and recovery objectives in patients undergoing TKA.

Population, Intervention, Comparator, and Outcomes (PICO)

This review examines adult patients undergoing TKA to determine whether interventions enhancing sleep quality can lead to a measurable reduction in postoperative pain. It compares outcomes for individuals who receive sleep interventions with those experiencing poor sleep or no intervention. In addition to pain management, the review investigates the role of improved sleep in promoting functional recovery, contrasting these outcomes with those in patients whose sleep is not addressed. Finally, it evaluates the broader impact of sleep optimization on overall recovery, including physical rehabilitation, psychosocial adjustment, and quality of life, in comparison to conditions of suboptimal sleep.

Materials and methods

Study design and search strategy

This study adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. The search strategy targeted five databases: PubMed, Embase, Ovid/MEDLINE, CINAHL, and Scopus. Initial searches commenced on September 13, 2024, and to ensure comprehensive coverage by including recent articles, a secondary search was conducted on November 15, 2024, using the same methodology. The search string “total knee” AND “sleep” was consistently applied across all databases and was developed in consultation with an experienced librarian. In Scopus, the prefix “TITLE-ABS-KEY” was included to restrict searches to titles, abstracts, and keywords. Filters were set to include only English-language primary literature published from 1999 to the search date.

Selection process and study inclusion criteria

The article selection was facilitated by Rayyan software (Rayyan, Qatar Computing Research Institute, Ar-Rayyan, Qatar), which managed duplicate removal and conducted screening at the title, abstract, and full-text levels. Studies were included if they focused on adult patients (18 years or older) who had undergone TKA and assessed sleep quality using validated tools, such as the PSQI, Epworth Sleepiness Scale (ESS), ISI, actigraphy, or structured sleep diaries. Studies were excluded if they did not include recovery outcomes related to pain, mobility, or functional improvement. Additionally, studies without validated sleep measures, those lacking TKA-specific recovery data, and non-primary literature – such as editorials, opinion pieces, surveys, or case reports – were excluded. Screening was conducted by two independent reviewers, with disagreements resolved through consultation with a third reviewer. A PRISMA diagram illustrating the search process is provided in Figure 1.

Figure 1: PRISMA flow diagram of included studies in systematic review.

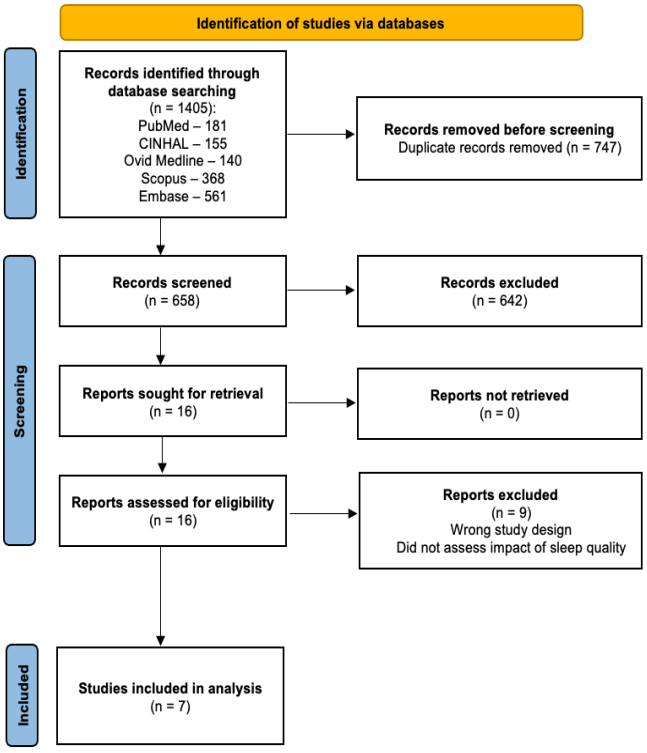

Table 1: Study features, methodology, and sleep quality assessments.

		Criteria				
Study (year)	**Study design**	**Inclusion**	**Exclusion**	**Validated sleep quality measure**	**Additional measure**	**Risk of bias**
Gibian et al. (2023)	Prospective observational cohort study	Age ≥18, BMI<45, smartphone ownership	Revision/bilateral TKA, pregnancy, narcotic dependence, neurological disorders, peripheral vascular disease, prisoners	PSQI	Fitbit Inspire HR wearable device	Low
Hamilton et al. (2023)	Prospective observational cohort study	Age ≥45, fluent in English, and meeting American College of Rheumatology criteria for KOA	Cognitive disorders, autoimmune disorders, recent MI, severe Raynaud symptoms, moderate-to-severe peripheral neuropathy	ISI	–	Medium
Mukartihal et al. (2022)	Prospective observational cohort study	Patients undergoing elective primary TKA, consenting to participate and complete outcome surveys	Revision/complex TKA, history of sleep disorders, psychiatric disorders, and prior knee surgeries	PSQI	–	Low
Owens et al. (2023)	Prospective observational cohort study	Age ≥45, KOA diagnosis, scheduled for unilateral TKA, proficient in English, stable medication use for one month prior	Cognitive disorders, cardiovascular conditions, peripheral neuropathy, pregnancy, and systemic inflammatory conditions (e.g., rheumatoid arthritis)	ISI	2-item Sleep and Pain Behavior Scale (SP2) developed for this study	Medium
Hamai et al. (2023)	Retrospective cohort study	Primary TKA performed ≥18 months prior to the study with patient-reported outcomes data	None explicitly mentioned, but focus was on patients with adequate follow-up and data	PSQI	–	High
Herrero-Sánchez et al. (2014)	Cross-sectional observational study	Elderly patients with TKA performed within one month of the study	Previous TKA, lower extremity or cervical surgery, radiculopathy, myelopathy, fibromyalgia, cognitive impairment, or rehabilitation within 6 months	PSQI	–	Medium
Hughes et al. (2018)	Prospective observational cohort study	Adults scheduled for primary TKA	Not explicitly listed	ISI	3-item Sleep-Pain Behaviors Survey (SPBS); actigraphy	Medium

Dashes (–) indicate not reported. BMI: Body Mass Index, TKA: Total Knee Arthroplasty, PSQI: Pittsburgh Sleep Quality Index, ISI: Insomnia Severity Index.

Risk of bias and quality of evidence

The ROBINS-I V2 tool (Risk of Bias in Non-randomized Studies of Interventions Version 2) was used to assess the quality of the studies. This approach facilitated a comprehensive evaluation of the studies

Risk of bias and quality assessment: Observational studies inherently carry a higher risk of bias compared to randomized controlled trials due to the absence of randomization and control groups. This limitation increases their vulnerability to confounding and selection bias, as the included populations may not accurately represent the broader patient population. Furthermore, observational studies often face information and measurement biases because of the lack of standardized outcome measures or blinding. Publication bias is also a concern, with studies reporting positive or significant findings being more likely to be published. Despite these challenges, observational studies, such as case-control and cohort studies, provide valuable insights, especially for conditions difficult to investigate through randomized trials. However, their findings tend to be associative rather than causal, and their generalizability is limited. These factors highlight the need for a cautious interpretation of their results.

Level of evidence and grade of recommendation: This systematic review encompasses studies including RCTs, cohort, observational, and retrospective studies. The evidence's overall level is categorized as Level 2, indicative of observational data frequently employed to report rare conditions or unique clinical outcomes. Observational studies, comprising well-designed cohorts, case-control, or large case series, generally fall under Level 2 evidence. While these studies deliver moderate-quality evidence, they may entail some bias risk due to confounding variables, lack of randomization, or incomplete data. These studies are valuable for identifying associations and generating hypotheses, yet they might lack the rigor associated with randomized controlled trials. Consequently, a Grade B recommendation is assigned based on this evidence level. This grade denotes consistent or moderately strong evidence suggesting that an intervention or finding is likely to enhance outcomes. Nonetheless, further validation through higher-level studies may be necessary to confirm its efficacy and generalizability.

Data extraction and statistical analysis

Data collection from all five databases was conducted by two independent authors (VMVJ, MN). They systematically extracted data into a customized spreadsheet to ensure consistency and accuracy across the studies. The variables gathered included patient demographics, sample sizes, sleep quality assessment tools, recovery metrics, and key findings. Numerical data, such as means and standard deviations, were recorded, while ranges were noted to account for study heterogeneity. A narrative synthesis approach was employed, focusing on trends, commonalities, and variations in the findings. Results were organized thematically to explore the influence of sleep quality on postoperative outcomes, including pain, mobility, and overall recovery trajectories. Adverse events were also documented. Discrepancies, if any, were resolved through consultation with a third reviewer.

Results

Overview of included studies

A search across five databases initially identified 1,405 studies. After removing duplicates and conducting abstract screenings and full-text reviews based on inclusion and exclusion criteria, seven articles were selected for inclusion in our systematic review. This entire process is detailed in the PRISMA flowsheet (Figure 1). All included studies had received the necessary ethical approval before publication. The studies were all observational in design; specifically, there were five prospective observational cohort studies, one retrospective cohort study, and one cross-sectional observational study. No randomized controlled trials met the inclusion criteria. Table 1 provides further details on the study characteristics, methodologies, and tools used to assess sleep quality. Four studies exclusively employed a single validated sleep measure, either the PSQI or the ISI, while three studies used at least one additional measure, such as self-created surveys, actigraphy, or other methods.

Impact of sleep quality on pain outcomes

Four studies investigated the impact of sleep quality on pain outcomes following TKA. Gibian et al. [14] found that patients who reported "very bad" sleep at 30 days postoperatively had significantly higher pain scores, with average VAS scores of 3.8 compared to 1.6 in those reporting "bad" sleep (P=0.010). Moreover, device-measured sleep duration remained stable postoperatively and did not show a significant correlation with pain outcomes (preoperative: 5.9 h; 60 days post-TKA: 5.6 h; 90 days post-TKA: 5.8 h). Hamilton et al. [15] reported that persistent perioperative insomnia was associated with higher pain scores at all postoperative time points. Participants with persistent insomnia showed a slower decline in WOMAC-Pain scores compared to those with improved insomnia, new insomnia, or no insomnia. Although all groups' WOMAC-Pain scores fell below the clinical threshold (≤ 30) at 12 months post-TKA, the persistent insomnia group had a less pronounced reduction, decreasing from 47.74 at baseline to 15.14 (P<0.05). Similarly, Mukartihal et al. [16] found that PSQI scores increased significantly during the first six postoperative weeks (mean 13.48 vs. preoperative mean 1.98, P<0.001); as sleep quality returned to near-baseline levels by 1 year (mean PSQI 2.10, P=0.15), Knee Society Scores (KSS) – which include pain measures – improved from a preoperative mean of 52.00 (9.98) to 71.67 (6.58) at 6 weeks and 85.49 (4.67) at 1 year postoperatively (P<0.001). Owens et al. [17] found that insomnia symptoms at 6 weeks postoperatively, indicated by peak ISI scores of 12.42, mediated the relationship between maladaptive presurgical sleep behaviors and long-term pain outcomes.

Impact of sleep quality on functional recovery

Four studies were included that assessed sleep quality and functional recovery. A retrospective review/observational study by Hamilton et al. [15] found that participants with persistent perioperative insomnia had significantly worse physical function at 6 weeks postoperatively, with WOMAC-Physical Function scores above the clinical threshold of ≤ 30 (M=36.80) and significantly higher than all other trajectories (P<0.05). Participants in the new insomnia group also had elevated scores (M=28.13) compared to the Improved Insomnia and No Insomnia groups (P<0.05). However, by 12 months, there were no statistically significant differences in physical function among groups. A similar review/observational study by Mukartihal et al. [16] reported that early postoperative sleep disturbances, reflected in elevated PSQI scores (mean 13.48 at 1 week postoperatively), were linked to delayed functional recovery, as measured by KSS. As sleep quality improved over time, functional outcomes also improved, with KSS rising from 71.67 at 6 weeks to 85.49 at 1 year. Owens et al. [17] identified maladaptive presurgical sleep behaviors as facilitators of poorer functional outcomes, as seen in WOMAC-Physical Function scores at 6 weeks (b=7.026, P=0.007). Hamai et al. [18] observed a significant association between better functional capability, indicated by a mean Knee Society Score of 62 (22), and fewer sleep disturbances at midterm follow-up.

Relationship between sleep quality and overall recovery trajectory

Herrero-Sánchez et al. [19] found that patients with poor sleep quality (mean PSQI score of 11.2) experienced significantly reduced physical function, as evidenced by lower SF-36 scores (40.8 [22.9] compared to 68.3 [19.9] in controls, P<0.001), and greater disability, indicated by higher WOMAC scores (35.0 [19.2] versus 23.71 [15.04], P=0.036). These findings underscore the detrimental impact of inadequate sleep on health-related quality of life, hindering engagement in daily activities during recovery. Additionally, Hughes et al. [20] demonstrated the longitudinal impact of maladaptive sleep-pain behaviors on recovery. Persistent insomnia symptoms, assessed with the ISI, were linked to heightened pain severity (B=0.32, P<0.001) and poorer physical function (WOMAC, B=1.71, P<0.01) over the first postoperative year.

Discussion

Our systematic review highlights the significant relationship between sleep quality and critical components of postoperative recovery following TKA. Multiple studies indicate that poor sleep, particularly persistent perioperative insomnia, is closely associated with increased pain levels, slower pain resolution, and delayed functional improvement. Patients with poor sleep consistently reported greater pain intensity at various postoperative stages, and those with similar sleep disturbances experienced prolonged impairments in physical function. For instance, Hamilton et al. [15] found that patients with persistent insomnia exhibited significantly worse physical function during early recovery. Notably, these differences are mostly diminished by the 12-month post-TKA mark, suggesting that while insomnia may initially hinder functional recovery, its long-term impact may be limited or requires further investigation. Furthermore, our findings show that inadequate sleep correlates with worse overall recovery trajectories, including diminished health-related quality of life and increased debilitation. Collectively, our observations suggest that proactively addressing sleep disturbances in the perioperative phase may be essential for optimizing pain management and functional recovery following TKA in adult patients.

A study by Nuñez et al. [21] also found that restorative sleep and regular physical activity were linked to improved physical function and reduced pain in individuals with long-term knee osteoarthritis. Patients who experienced better sleep quality and participated in physical activity showed enhanced functional capacity and an improved overall quality of life. These findings emphasize the interconnected role of sleep, aligning with previous research indicating that sleep disruptions can intensify pain perception [22,23]. This suggests that optimizing sleep quality may be crucial for rehabilitation and functional recovery following TKA.

Unlike previous studies that have demonstrated a notable connection between sleep quality and functional recovery, Van Meirhaeghe et al. [8] found a different pattern. Their study revealed that although sleep quality improved following total knee and hip arthroplasty, it was more closely linked to patient satisfaction than to functional outcomes. Despite a significant number of patients reporting better sleep postoperatively, the association between improved sleep and enhanced physical function remained weak according to their findings. This suggests that factors other than sleep might more significantly influence postoperative functional recovery. Although other studies have

documented that this relationship may be mediated by inflammatory pathways and psychosocial stressors [24,25], the existing discrepancies highlight the need for further investigation into the specific mechanisms by which sleep contributes to rehabilitation outcomes in arthroplasty patients.

Given the variability in findings about the relationship between sleep quality and functional recovery, a targeted clinical approach to perioperative sleep management could optimize postoperative outcomes for TKA patients. Identifying sleep disturbances pre-surgery allows for early interventions, such as cognitive-behavioral therapy for insomnia (CBT-I) or pharmacologic treatment, when appropriate. Incorporating sleep-focused education into rehabilitation programs may also improve patient adherence to recovery protocols, potentially enhancing pain control and mobility. Although optimizing sleep is crucial in postoperative care, it should be integrated with other essential rehabilitation strategies – such as structured physical therapy and multimodal pain management – to ensure a comprehensive and individualized recovery plan.

Future directions and recommendations

We offer several recommendations. First, this review identified a significant correlation between sleep and both pain and functional recovery. Future research should explore interventions aimed at optimizing both perceived and objective sleep quality. Additionally, our search did not identify any randomized controlled trials (RCTs). To clarify the impact of sleep quality on postoperative pain and functional outcomes, we recommend that researchers employ a robust RCT design. Lastly, tailored interventions, such as cognitive-behavioral therapy for insomnia (CBT-I) and pharmacological treatments, warrant further investigation in diverse TKA populations. These interventions may help reduce sleep disturbances and enhance recovery.

Limitations

This study presents several limitations. First, although there is literature on the association of sleep with postoperative outcomes, most studies are observational or retrospective. Additionally, methodological heterogeneity, especially regarding the recovery metrics employed, underscores the need for standardized protocols in future research. Such standardization would facilitate future meta-analyses. Despite these limitations, we consider this article important as it provides up-to-date information, identifies gaps in the literature, and offers recommendations and future considerations for researchers. These contributions are crucial for improving sleep and postoperative outcomes in patients undergoing TKA.

Conclusion

This systematic review assesses the relationship between sleep quality and recovery outcomes in patients undergoing TKA. Poor sleep quality consistently correlates with increased postoperative pain, slower functional recovery, and diminished overall recovery trajectories. This dynamic between sleep disturbances and recovery emphasizes the need to integrate sleep-focused interventions into perioperative care. However, the variability in methodologies and reliance on subjective measures limit the broader applicability of current findings, highlighting the need for standardized protocols and comprehensive longitudinal studies.

Future research should assess the effectiveness of interventions like cognitive-behavioral therapy for insomnia and utilize objective tools such as actigraphy in diverse TKA populations. Prioritizing sleep quality in postoperative care enables clinicians to address modifiable factors, thereby enhancing recovery and ultimately improving the quality of life for patients undergoing TKA.

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J Surg Med. 2025;9(11):251-254.
https://doi.org/10.28982/josam.8139

JOSAM

Journal of Surgery and Medicine

e-ISSN: 2602-2079

Case report
https://jsurgmed.com/

Pancreaticopleural fistula – An unusual indication of intercostal tube drainage

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Informed Consent
The authors stated that the written consent was obtained from the patient presented with images in the study.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2025 October 9

Abstract

Pancreatitis, whether acute or chronic, can lead to a spectrum of local and systemic complications due to the extravasation of inflammatory mediators in the vicinity of the gland. One such rare complication is the development of a pancreaticopleural fistula (PPF), typically presenting as a unilateral or, less commonly, bilateral pleural effusion accompanied by respiratory symptoms. A young male in his thirties with a history of heavy alcohol consumption presented with dyspnea, upper abdominal pain, and a recent episode of an alcohol binge, one month ago. Clinical examination revealed epigastric tenderness in the epigastrium with decreased breath sounds, and a diagnosis of acute pancreatitis was made. This was confirmed by elevated serum lipase and bilateral pleural effusion on chest X-ray. Given his partial response to conservative management, a decision was taken for bilateral tube thoracostomy. Fluid analysis confirmed the diagnosis of PPF. He was subsequently started on somatostatin analogs and parenteral nutrition. He responded well to the above treatment and was discharged after a week. While PPF is a recognized cause of unilateral pleural effusion, bilateral involvement is uncommon. The condition often presents predominantly with chest symptoms, with a paucity of abdominal complaints. It should be suspected that alcoholic pancreatitis responds poorly to usual conservative therapy. The biochemical analysis of the aspirated pleural fluid reveals significantly increased amylase levels, which clinches the diagnosis. Cross-sectional imaging helps in characterizing the primary disease in the pancreas and in delineating the ductal anatomy. Endoscopy is both diagnostic and therapeutic, as it involves placing a stent in the main pancreatic duct (MPD). The management involves a combination of medical, endoscopic, and surgical modalities. Medical management is successful in a majority of cases by using somatostatin analogs with nutritional support. Placement of an intercostal tube hastens recovery and reduces the duration of hospitalization. Surgical management by distal pancreatectomy with pancreatojejunostomy is reserved for a small subset of patients. Hence, patients with PPF rarely present with bilateral pleural effusion and are an indication for tube thoracostomy with successful results.

Keywords: pleural effusion, intercostal tube, pancreaticopleural fistula, octreotide, endoscopy, Contarini syndrome

Introduction

Bilateral pleural effusion is commonly seen in systemic disorders such as congestive cardiac failure, cirrhosis, end-stage renal disease, hypoalbuminemia, malignancy, autoimmune disease, or a combination of these etiologies. In contrast, acute pancreatitis is an uncommon etiology of bilateral effusion [1].

In rare cases, acute or chronic pancreatitis can lead to the formation of internal fistulae. The most common clinical presentation includes dyspnea with or without accompanying abdominal pain. PPF is typically diagnosed by the increased levels of amylase in pleural fluid and cross-sectional imaging such as magnetic resonance cholangiopancreatography (MRCP) and contrast-enhanced computed tomography (CECT). These imaging techniques help visualize the fistulous tract, the anatomy of the MPD, and changes in pancreatic parenchyma [1-3]. Diagnosing PPF requires skilled clinical assessment and is managed using various modalities, including medications, endoscopic stents, and surgery. This article presents a unique case of PPF, which manifested as bilateral pleural effusion and was managed by bilateral thoracostomy.

How to cite: Kalra T, Agarwal A. Pancreaticopleural fistula – An unusual indication of intercostal tube drainage. J Surg Med. 2025;9(11):251-254.

Case presentation

History

A 30-year-old male presented with complaints of dyspnea for one week, which was aggravated in the supine position. He reported a recent episode of alcohol binge drinking approximately a month back, which was followed by upper abdominal pain. He self-medicated with over-the-counter pain medications, which provided partial relief. However, he continued to experience abdominal discomfort, particularly after meals. He denied vomiting, high-grade fever, or cough. Notably, he had a similar episode of upper abdominal pain six months earlier, which was managed conservatively at a local hospital. There was no other significant past medical or surgical history.

Examination

On examination, he was tachypneic and tachycardic with signs of malnutrition and dehydration. Abdominal examination revealed tenderness and fullness in the epigastrium region. Respiratory examination showed diminished vesicular breath sounds, more on the left side. The remainder of the systemic examination was normal. Based on his symptoms, history of alcohol use, and examination findings, a provisional diagnosis of acute pancreatitis with pleural effusion was made.

Diagnosis

Initial laboratory investigations revealed leukocytosis with elevated serum amylase (1729 IU/L) and lipase (1249.7 IU/L) levels. A chest roentgenogram (X-ray) demonstrated moderate pleural effusion on the left side and mild pleural effusion on the right side, with a tracheal deviation to the right (Figure 1).

Management

The patient was admitted and managed with intravenous fluids, analgesics, and supplemental oxygen via a face mask at 4L/minute. As his oxygen saturation at room air was low, at 88%, he was maintained in a reclining posture.

Despite initial therapy for 3 days, he reported partial symptom relief. He underwent CECT of the thorax and abdomen, which revealed acute pancreatitis with acute pancreatic fluid collection (APFC) near the tail of the pancreas and extending to the perisplenic area and moderate bilateral pleural effusion without atelectasis (Figure 2).

Due to persistent dyspnea, tube thoracocentesis was performed bilaterally, draining 400 ml of fluid on the left side and 200 ml of fluid on the right side (Figure 3). The aspirated fluid was serous and was sent for biochemical and microbiological analysis, which revealed markedly elevated pleural fluid amylase levels: 51416 IU/L on the left side, and 10412 IU/L on the right side. This confirmed the diagnosis of a PPF.

Meanwhile, the patient showed significant improvement in dyspnea following drainage. Subsequently, he was started on subcutaneous octreotide (100 mcg every 8 hours), kept nil by oral, and initiated on total parenteral nutrition (TPN).

Over the next two weeks, there was a progressive decline in his thoracostomy output, and the patient's overall well-being improved. A follow-up chest roentgenogram (X-ray) showed a resolution of effusion on the right side, leading to the removal of the right thoracostomy tube. TPN was gradually weaned off, and oral intake resumed.

The patient was discharged with a left-sided thoracostomy tube in situ, which was subsequently removed two weeks later during follow-up after output was ceased. Repeat imaging confirmed full pulmonary re-expansion (Figure 4).

Figure 1: Chest roentgenogram with bilateral pleural effusion.

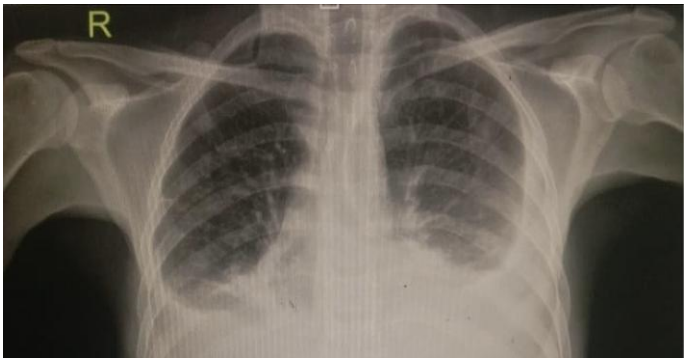


Figure 2: CECT chest and abdomen with bilateral pleural effusion and acute pancreatitis with APFC.

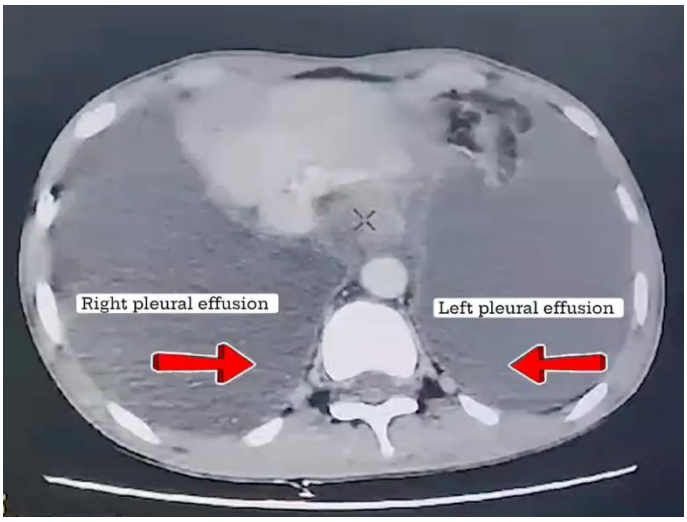


Figure 3: Chest roentgenogram with bilateral intercostal tubes and resolution of pleural effusion.

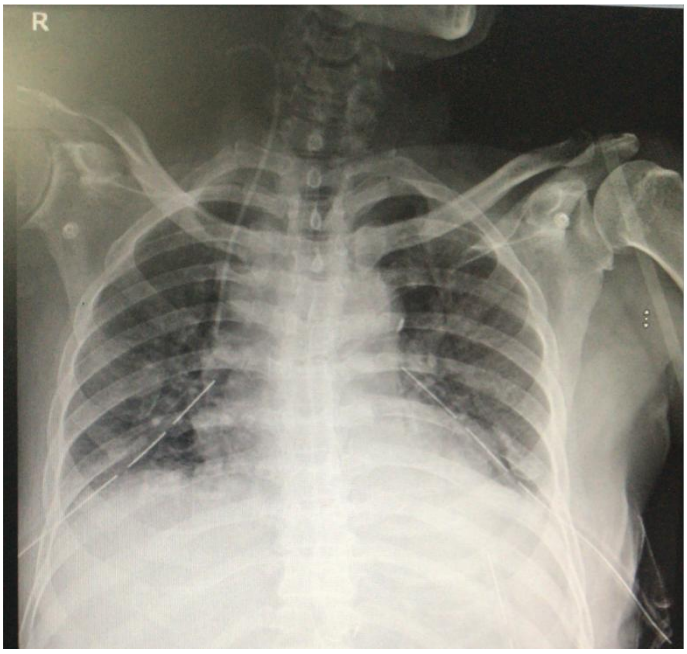
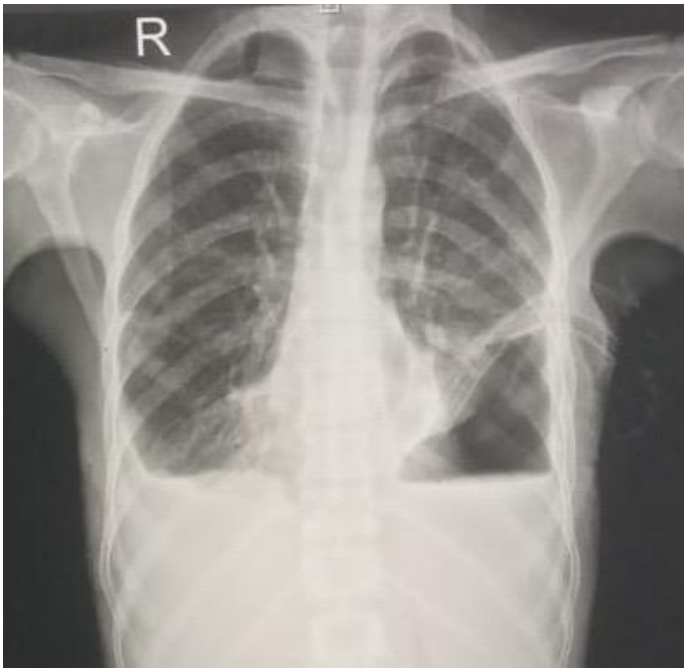


Figure 4: Chest roentgenogram with only the left side intercostal tube.



Discussion

PPF was first identified as a separate complication of pancreatitis in the 1960s and 70s and has remained an uncommon and difficult entity to treat [1]. The incidence of PPF is 0.4% in patients with chronic pancreatitis, and it usually presents as a left-sided pleural effusion, causing dyspnea [2]. The incidence of right-sided effusion in PPF is around 20%, while bilateral effusion is rarer (<15%) [3]. On the contrary, PPF accounts for 1% of cases of pleural effusion [4].

PPF is caused either by the direct extension of a pseudocyst across the diaphragm or by the formation of a fistulous tract between the pancreas and the pleural spaces. Ethanol is implicated in the secretion of insoluble pancreatic proteins that calcify and occlude the MPD. The pancreatic fluid leaks into the retroperitoneum. From there, it usually moves cranially due to the transdiaphragmatic pressure gradient between the abdominal and pleural cavities [5]. PPF is characterized by the rapid accumulation of significant fluid and its refractoriness [4,6]. Persistent PPF can lead to inadequate lung expansion (trapped lung) and has been reported in a few case reports.

Diagnosing PPF involves differentiating it from reactive and inflammatory pleural effusion in acute pancreatitis. Although PPF is common on the left side, it may also occur on the right side or bilaterally [7]. In cases of bilateral pleural effusion, one must rule out Contarini syndrome.

This syndrome was first described in Francesco Contarini in the 16th century in Venice, who had developed bilateral pleural effusion. His autopsy revealed right-sided pleural effusion due to cardiac failure and a contralateral empyema. The presence of two different etiologies for bilateral pleural effusion occurs in 5% of cases. This condition remains underdiagnosed as experts recommend doing a bilateral thoracocentesis only if [8]:

1. Unilateral lung parenchymal involvement
2. Significant disparity in the size of effusions
3. Markedly different attenuation values on CECT
4. Atypical clinical findings (e.g., fever or pleuritic chest pain in the presence of decompensated cardiac failure)
5. Resolution of pleural effusion only on one side

The typical patient of PPF is a middle-aged, chronic alcoholic male presenting with breathlessness, cough, and chest pain but no abdominal pain [9]. Less commonly, it may occur in cases of gallstone-induced, traumatic, and idiopathic pancreatitis [10]. The predominance of cardiopulmonary symptoms and lack of abdominal features explains the delay in diagnosis (median of 5.6 weeks) [11]. The presented case aligns with this profile, highlighting the importance of clinical suspicion in such scenarios.

Elevated pleural fluid amylase is a hallmark finding and serves as a suitable diagnostic test [12]. In the review by Rockey and Cello [11], the mean recorded value of pleural fluid amylase was found to be 18,450 IU/L (range: 1,830-164,187 IU/L). The value for our patient lies within the range mentioned in the above review. Various other pathologies with increased amylase levels, such as adenocarcinoma of the lung and female genital tract, pleural mesothelioma, and oesophageal perforation, must be ruled out [13].

A high degree of suspicion and clinical acumen is required to accurately diagnose this distinct entity. Imaging modalities help identify PPF and make therapeutic decisions. MRCP offers non-invasive visualization of ductal anatomy, aiding in stratifying further management [10]. MRCP has a sensitivity of 80% for detecting PPF, compared to 78% with endoscopic retrograde cholangiopancreatography (ERCP) [14].

The treatment of PPF is multidisciplinary and involves medical therapy, and endoscopic and/or surgical interventions. The initial conservative approach, including observation and medical therapy, is effective in 31-45% of patients [10]. Somatostatin analogs, such as octreotide, reduce the output from MPD, thereby leading to early fistula closure. The duration of medical treatment is unclear, with a suggested period of 2 to 4 weeks before considering alternative interventions [11]. These patients require frequent thoracocentesis. There are various case reports and series where the patients have been managed with medical therapy with pleural drainage only, without the need for endoscopy or surgery [14]. Our patient was managed similarly by a combination of medical therapy and placement of tube thoracostomy tubes bilaterally.

ERCP with stent placement has revolutionized nonoperative therapy for PPF [15]. Stents aid by mechanically occluding the fistulous communication and also dilating duct strictures [4]. Success rates vary, depending on patient selection and ductal anatomy. Surgical intervention, though definitive, is typically reserved for cases unresponsive to medical or endoscopic treatments but has a higher curative rate of up to 90% [4]. It includes pancreatojejunostomy with or without pancreatic resection.

Conclusion

In patients with a history of acute or chronic pancreatitis, all pleural effusions may not be assumed to be reactive. PPF may be considered in the list of differential diagnoses, especially in cases of bilateral effusions. Elevated pleural fluid amylase levels, coupled with imaging methods such as ERCP, MRCP, and CECT, confirm the diagnosis. Initially, a conservative, non-operative approach by use of drugs and pleural drainage remains effective in many cases, without the need for endoscopic intervention.

Surgical intervention is considered the last resort for patients who fail both conservative and endoscopic approaches.

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J Surg Med. 2025;9(11):255-257.
https://doi.org/10.28982/josam.8232

JOSAM

Journal of Surgery and Medicine

e-ISSN: 2602-2079

Case report
https://jsurgmed.com/

Pseudomonas plecoglossicida meningitis: A potential evolving human pathogen and a threat to public health

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Informed Consent
The authors stated that the written consent was obtained from the patient presented with images in the study.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2025 November 6

Abstract

Pseudomonas plecoglossicida, a well-known fish pathogen, seems to have evolved into a human pathogen, inciting a public health concern. We present a rare case of community-acquired *Pseudomonas plecoglossicida* meningitis in a healthy adult. A 49-year-old male, a "Galamsey" (water-based, small-scale gold mining) operator, presented with one week's history of headache, neck and whole-body stiffness. On further questioning, he revealed that he was unable to open his mouth and could not walk due to severe back pain and body stiffness. There was a preceding history of sore throat of four days duration. Examination revealed nuchal rigidity, and positive Kernig's and Brudzinski's signs. Cerebrospinal fluid (CSF) analysis showed high protein and glucose levels, with normal cell counts. A culture of CSF isolated gram-negative bacilli, found to be *Pseudomonas plecoglossicida*, was sensitive to Ceftazidime, Cefepime and Meropenem. Clinical features were completely resolved without any clinical evidence of complications after a full course of tailored treatment. We report, to the best of our knowledge, the first case of *Pseudomonas plecoglossicida* meningitis with some diagnostic challenges. This underscores the urgent need for establishment of public health surveillance systems to identify similar cases especially in "Galamsey" zones in Ghana and similar settings, in order to mitigate their pathogenic burden.

Keywords: *Pseudomonas plecoglossicida*, *Pseudomonas*, meningitis, human pathogen, threat, public health

Introduction

Pseudomonas plecoglossicida is a gram-negative rod-shaped, flagellated bacterium in the pseudomonas putida group. It is a well-established pathogenic organism in fish. It has a number of virulence factors which enable it colonize the host fishes and produce diseases including visceral white spot disease, and hemorrhagic ascites in ayu fish (plecoglossus altivelis), giving it its name [1,2]. This organism is a culprit in disease outbreaks in aquaculture [3]. Nonetheless, the organism has not been well-documented as a cause of human disease. Few case reports, however, described pseudomonas putida, the "species typica" of the group, as a rare cause of pneumonia and meningitis in humans [4-6]. This draws attention to a potential paradigm shift of gradual transition of this organism from a fish pathogen to a human pathogen. Probably, the organism might have acquired special environmental and genetic adaptations. This is, however, subject to further exploration in future studies. Generally, Pseudomonas infections are most often hospital-acquired or encountered in immunocompromised patients [7,8]. Moreover, Pseudomonas infections are known for their treatment challenges, due to their resistance to the common antibiotics used in clinical practice [9-13]. Thus, this case posed a threat to human life and public health. No study had yet reported the organism as a causative agent for bacterial meningitis in humans, to the best of our knowledge. We report a rare case of community-acquired *Pseudomonas plecoglossicida* meningitis in a healthy adult, recorded in a district hospital in Ghana. Additionally, we share our experiences with the management and some diagnostic challenges.

How to cite: Ahiakpa AK, Buamah EO, Eisa-Ansah AV, Ohene-Yeboah MK, Afful A, Akuribire F. *Pseudomonas plecoglossicida* meningitis: A potential evolving human pathogen and a threat to public health. J Surg Med. 2025;9(11):255-257.

Case presentation

Clinical History

A 49-year-old African male and small-scale miner (*Galamsey* operator) presented to the emergency department with a one-week history of headache, generalized body stiffness and severe back pain worsened by walking. On further questioning, he had difficulty opening the jaw, and an inability to walk due to stiffness of the lower limbs and back. These symptoms were preceded four days earlier by a low-grade fever, sore throat, and difficulty swallowing. He denied any photophobia, phonophobia, altered mental state, or personality changes.

Physical Examination

A middle-aged male wheeled into the emergency room. He was not in respiratory distress, nor warm to the touch. Vital signs checked were within normal ranges (T-37.0 ^{0}C, BP-118/81 mmHg, PR-84 bpm, RR-20 cpm, SPO2-99% on room air). A neurological exam revealed a conscious and alert patient, with a Glasgow Coma Score (GCS) of 15/15. He was oriented to time, place, and person. His pupils were equal in size (about 2 mm) and equally reactive to light directly and consensually. There was nuchal rigidity with positive Kernig and Brudzinski signs. Power was 5/5 in all limbs and deep tendon reflexes were normal. There was no lateralizing sign or focal neurological deficits. Examination of other systems was unremarkable.

Differential Diagnoses

An initial impression of meningitis was made based on clinical findings. However, this was closely seconded by a differential diagnosis of tetanus, However, this was less likely, given the absence of previous injury, and clinical features pointing more to meningism than skeletal muscle spasm of tetanus.

Lumbar Puncture (LP) Procedure

Under aseptic conditions in the operating theater, the patient was positioned in a lateral decubitus, knee-chest position. He was exposed from upper trunk to the infra-gluteal folds. The site was cleaned with povidone iodine, Savlon, and methylated spirit and draped with a sterile drape. A sterile spinal needle was introduced into the L3-L4 interspace. About 5 mls of clear CSF was obtained into a plain universal CSF bottle, covered, and transported air-tight to the laboratory for analysis.

Results of Laboratory Investigations

A full blood count showed moderate anemia and severe thrombocytopenia (Table 1). CSF analysis revealed clear CSF with high protein, low glucose and normal cell counts (Table 2).

CSF culture showed gram-negative bacilli, *Pseudomonas plecoglossicida* isolated. Antimicrobial sensitivity testing showed the organism was sensitive to Ceftazidime, Cefepime and Meropenem.

Treatment/Treatment Response

The patient was started on intravenous (IV) Ceftriaxone (Rocephin) 2g 12 hourly from day 1-7 of admission, while awaiting CSF analysis/culture and sensitivity results. LP was done on Day 2 of admission, but results were obtained on Day 8 of admission. The antibiotic was then immediately switched to IV Ceftazidime 2g 8 hourly for an additional 14 days, making a total of 21 days of IV antibiotic therapy. Symptomatic treatment was also given, including analgesia for headache and generalized body pains, and skeletal muscle relaxants for neck and body stiffness.

After 10 days of IV antibiotic therapy, the patient began to demonstrate significant improvement, and symptoms resolved gradually over this period. He took his first step unaided on Day 10 of treatment, though with an unsteady gait. He continued with a Zimmer frame, and then later, without the Zimmer frame by day 18 of antibiotic treatment. At this time, all stiffness and pain associated with walking had resolved. He was discharged after marked clinical improvement on Day 22 of admission.

Follow-up

The patient was reviewed at the medical outpatient department two weeks after discharge. He was completely free of symptoms and signs, and he was walking with a normal gait at this time.

Ethical and Privacy Statement

A written and signed informed consent (from the hospital) was obtained from the patient under no duress to publish the details of his case. He was made aware that this case report would only be published for improvement of the scientific knowledge base, clinical practice, and the health of the public, but not for commercial purposes. Additionally, all efforts were made to anonymize our patient, and all confidential patient information attached were de-identified.

Table 1: Patient's full blood count (FBC) results before treatment

Findings	Ref range	Unit	Interpretation
Hb-10.7	13.0-17	g/dl	Low
WBC-5.0	3.5-10.5	x 10^3/µL	Normal
PLT-35	150-450	x 10^3/µL	Low (Severe Thrombocytopenia)

Hb: Hemoglobin, PLT: Platelet count, WBC: White Blood Cell count

Table 2: Patient's CSF analysis (macroscopy, biochemistry and microscopy) results

CSF Analysis	Findings	Ref Range	Unit	Interpretations
Appearance	Clear and colorless			
Total Protein	0.54	0.15-0.45	g/L	High*
Glucose	1.7	2.2-3.89	mmol/L	Low*
Chloride	127	120-130	mmol/L	Normal
Polymorphs	0	0-2	/µL	Normal
Lymphocytes	0	0-5	/µL	Normal
Erythrocytes	1	0	/µL	-
Random Blood Sugar (Just before LP)	7.1	3.5-7.8	Mmol/L	Normal

* remarkable finding, CSF: Cerebrospinal Fluid, LP: Lumbar Puncture

Table 3: Patient's full blood count (FBC) results after treatment

Findings	Ref range	Unit	Interpretation
Hb-13.0	13.0-17	g/dl	Normal
WBC-4.20	3.5-10.5	x 10^3/µL	Normal
PLT-157	150-450	x 10^3/µL	Normal

Hb: Hemoglobin, PLT: Platelet count, WBC: White Blood Cell count

Discussion

We present a case of *Pseudomonas plecoglossicida* meningitis in a healthy adult male, with an upper respiratory tract infection as the possible focus. We also share our experiences with management and some diagnostic challenges. Of the classic triad of fever, neck stiffness, and altered mental status mostly seen in cases of bacterial meningitis in adults [14], our patient exhibited only neck stiffness at presentation.

The cerebrospinal fluid (CSF) biochemistry revealed low glucose and elevated protein, consistent with bacterial meningitis, as per findings established by other studies [15,16]. However, a notable deviation detected was the absence of white cells (polymorphs or lymphocytes) in the CSF. This may be due to a low antigenicity or virulence of the organism, resulting in a reduced inflammation response, though this hypothesis warrants further exploration in future studies. There was also a finding of severe thrombocytopenia, typically associated with cases of bacterial meningitis and an indicator of poor prognosis [17].

Interestingly, the patient had no bleeding complications, and platelet counts normalized with treatment (Table 1 and Table 3) without any hemorrhagic sequelae.

Pseudomonas aeruginosa is more commonly implicated in adult bacterial meningitis as compared to other Pseudomonas species. Sadly, it is usually associated with a worse prognosis [18]. In contrast, our patient responded well to tailored antibiotic therapy, which may indicate a less virulent disease course. Nonetheless, this is just a single case whose report does not provide conclusive evidence for scientific inferences. Further studies are, therefore, necessary to evaluate this organism's pathogenic process in humans.

Generally, *Pseudomonas species* are known to be largely environmental, dwelling in soils, natural water bodies on land, and fomites or instruments in health facilities [19,20]. Thus, most infections in humans are opportunistic and nosocomial in nature. Our patient's occupation as a Galamsey miner, involving digging and washing gold frequently in rivers, underpins a probable environmental exposure to these organisms as the source of infection. As such, it provides a significant potential causal link between the prior exposure to source (water) and the disease (meningitis) emergence. Therefore, this case brings on board more scientific evidence to fuel the ongoing fight against Galamsey in Ghana.

Limitations

We encountered a few challenges in management of the case. Due to the low socioeconomic status of our client, we were unable to do concurrent cultures of throat, blood, and urine samples. However, combining the clinical presentation/context, we believed that the primary focus of infection was the prior upper respiratory tract. In addition, we could not do a repeat CSF analysis/culture to ascertain complete clearance of the infection and resolution of CSF biochemical parameters post-treatment. However, after the full (21 days) course of parenteral antibiotic treatment, the patient improved with almost complete resolution of clinical signs and symptoms before he was discharged.

Conclusion

We report, to the best of our knowledge, the first case of *Pseudomonas plecoglossicida* meningitis in humans, per the current state of published reports. Hence, clinicians should be mindful of this with a high index of suspicion, considering the atypical clinical features of this type of meningitis. Public health surveillance systems should, therefore, be instituted to look out for such cases, especially in mining areas, as well as communities along the banks of rivers used for Galamsey activities in Ghana. Well-organized studies are needed in the future to support our findings and explore factors contributing to the evolution of the organism into a human pathogen.

Acknowledgements

We would like to express our gratitude to our patient and his wife for giving us consent to publish this case. We would also like to thank the management and ethical committee of Catholic Hospital, Battor, for giving us the approval and the support to proceed with this publication. We are most importantly grateful to Almighty God for inspiring us to take this bold step.

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