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ORIGINAL RESEARCH

The incidence, management, and outcomes of stage IIIB cervical cancer in a middle-income setting

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Background: Cervical cancer is the second most common cancer in South Africa, and most women present with stage III disease. Hydronephrosis is a frequent complication of advanced disease, and it is associated with poorer clinical outcomes.

Aim: This review aims to evaluate the management and outcomes of patients with stage IIIB cervical cancer and determine if the presence of hydronephrosis adversely influences the outcome in this disease stage.

Methods: A retrospective audit was conducted to assess the clinical data of patients treated for stage IIIB cervical cancer at Groote Schuur Hospital (GSH) between January 2017 and December 2018. The data collected included demographics, human immunodeficiency virus (HIV) status, comorbidities, pelvic sidewall involvement, presence of hydronephrosis, treatment intent and modalities, nephrostomy referral, treatment response, and survival outcome.

Results: A total of 132 patients were deemed eligible for our study, with a mean age of 52 years. The median overall survival (OS) was 15 months, and the median disease-free survival (DFS) for patients who completed radical treatment was 13 months. HIV status was the only factor that affected OS ($p = 0.05$) and DFS ($p = 0.03$). Neither age nor the presence of hydronephrosis influenced OS or DFS ($p > 0.05$).

Conclusion: Hydronephrosis did not affect OS or DFS. HIV was associated with an increased incidence of stage IIIB cervical cancer, and a negative prognostic factor for OS and DFS.

Keywords: cervical cancer, HIV, hydronephrosis, middle-income countries, radiotherapy, stage IIIB cervical cancer, cervical cancer prognosis

Introduction

Cervical cancer is the fourth most common cancer among women globally, and the fourth leading cause of cancer death in women, with an estimated 604 000 new cases and 342 000 reported deaths in 2020.[1] In 2020, almost 90% of new cases and deaths due to cervical cancer were recorded in low- to middle-income countries (LMIC), with the highest regional incidence and mortality in sub-Saharan Africa. This is because of limited access to preventative measures, resulting in advanced disease presentation.[1] The incidence of cervical cancer in developing countries remains high due to a combination of factors: absence of effective screening programmes, limited access to health services, poor awareness about preventative measures, including human papillomavirus (HPV) vaccination and screening, poverty, and low socioeconomic status.[2,3]

In an upper middle-income setting, like South Africa, the incidence of cervical cancer is higher than in Western countries. In South Africa, cervical cancer is the second most common cancer and the leading cause of cancer-related deaths.[4] This is largely due to coinfection with HIV and acquired immunodeficiency syndrome (AIDS), which is known to increase the risk of HPV infection. Women are typically younger and present with more advanced disease at the time of diagnosis.[5]

In 2018, South Africa had 6 268 new histologically confirmed cases of cervical cancer, comprising 15% of all cancers diagnosed in women that year. Breast cancer accounted for 23% of newly diagnosed cancers.[6] Based on the 2018 Groote Schuur Hospital (GSH) Gynaecological Oncology Unit annual report, there appears to be a continuous increase in cervical cancer incidence over the years, with a total of 174 newly diagnosed cases documented in 2018.[7] This represented a 20% incidence increase from 2007. The proportion of early-stage disease increased from 60 in 2007 to 80 in 2018, while the proportion of advanced-stage disease has remained stable. Stage III disease remains the most common presenting stage, accounting for 43.7% of all newly diagnosed cervical cancer cases.[7]

Cervical cancer is staged clinically, and the International Federation of Gynaecology and Obstetrics (FIGO) staging is the preferred system. It is less resource-intensive, more sensitive in detecting locally advanced disease, and identifies patients who are poor surgical candidates.[8] In 2018, FIGO revised the staging system of cervical cancer to improve prognostication and treatment planning.[9] Stage III cervical cancer was revised to include pelvic nodes (IIIC1) and para-aortic nodes (IIIC2).[9]

The ureters are in close anatomical proximity to the cervix. Tissue from malignant cervical tumours can compress the urinary outflow, directly invade the ureter, or result in ureteral scarring or stricture.[10,11] Hydronephrosis is a frequent complication in advanced disease, present in almost 50% of patients with advanced cervical cancer, and is associated with worse outcomes.[12] Unilateral or bilateral hydronephrosis can

result in renal dysfunction and limit the use of concurrent radiosensitising chemotherapeutic agents, like cisplatin, which has proven survival benefit.[13,14]

Numerous studies concluded that the presence of hydronephrosis is a negative prognostic factor for cervical cancer, with the mean survival of patients with unilateral hydronephrosis being significantly longer than that of those with bilateral hydronephrosis.[15] However, it remains unclear whether ureteral stent placement or percutaneous nephrostomies are of any benefit and improve survival outcomes for patients with bilateral hydronephrosis.[15]

While the outcomes of patients with stage IIIB cervical cancer presenting with hydronephrosis have been studied at length, data are limited on patients with pelvic sidewall (PSW) involvement without hydronephrosis and normal renal function. It stands to reason that there may be a difference in survival outcomes between these two groups of patients that fall within the same clinical stage of IIIB, with the premise that patients without hydronephrosis have a more favourable outcome.

There is also scant data on the management and outcomes of women with stage IIIB cervical cancer in low- to middle-income settings. GSH is one of two tertiary-level hospitals in Cape Town, South Africa. This study specifically focuses on the management and care of stage IIIB cervical cancer at GSH, providing a snapshot of advanced cervical cancer in a middle-income setting. This retrospective review aims to evaluate the management and outcomes, specifically overall survival (OS) and disease-free survival (DFS), in patients with stage IIIB cervical cancer in a public hospital within a middle-income context.

Methods and materials

This retrospective, descriptive audit was conducted at the Department of Radiation Oncology at GSH in Cape Town, South Africa. The study reviewed the clinical data of patients who received treatment for stage IIIB cervical cancer at GSH between 2017 and 2018. Data collection involved reviewing clinical records and accessing information from the electronic patient database at GSH and the Gynaecological Cancer Research Centre (GCRC) database (HREC RO16/2013) at the University of Cape Town. The GCRC database is dedicated to research programmes addressing the challenges faced by patients diagnosed with gynaecological cancers.

Eligible patients had a histologically confirmed diagnosis of cervical cancer, including both squamous cell carcinoma and adenocarcinoma, with disease staged as IIIB according to the 2009 FIGO classification. Patients were excluded if they had stages I, II, IIIA, or IV disease, or pre-existing renal dysfunction at diagnosis, defined as a serum creatinine level > 90 µmol/L (per National Health Laboratory Service criteria at GSH).

At the time of the study, the standard treatment protocol for stage IIIB cervical cancer at GSH consisted of:

- Definitive concurrent chemoradiation (CCRT)
- External beam radiotherapy (EBRT) using the volumetric modulated arc therapy technique.
- Total EBRT dose: 46 Gy in 2 Gy fractions, delivered to the cervix, uterus, and elective lymph nodes.
- Concurrent chemotherapy with weekly cisplatin or carboplatin at 40 mg/m^2.
- Intracavitary brachytherapy with a total dose of 28 Gy in four 7 Gy fractions, prescribed to Point A, which is a standardised point located approximately 2 cm superior along the tandem from the cervical os and 2cm lateral from the tandem.

Patient records meeting the above criteria were reviewed to obtain information on age, HIV status, comorbidities, baseline haemoglobin and creatinine, presence or absence of PSW involvement, presence or absence of hydronephrosis, renal impairment at commencement or during treatment, treatment intent and modalities, percutaneous nephrostomy referral, nephrostomy-related complications, and patient compliance with treatment.

The study's primary objectives were to determine the treatment outcomes (OS and DFS) of patients presenting with stage IIIB cervical cancer and hydronephrosis. As part of the primary objective, we also aimed to determine the degree of hydronephrosis (unilateral/bilateral), percutaneous nephrostomy rates, nephrostomy complication rates, and successful completion of concurrent chemoradiotherapy in this group. The secondary objectives were to determine the overall incidence of stage IIIB cervical cancer during this period and identify other factors that may significantly influence the outcome of patients presenting with stage IIIB cervical cancer.

All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 29. Statistics for numerical data included descriptive analysis and measures of central tendency. A Cox regression analysis was used to determine the effect of age, HIV status, and comorbidities on OS and DFS. Statistical significance was accepted at $p \leq 0.05$.

The study was approved by the Departmental Research Committee, hospital management, and the Human Research Ethics Committee of the Faculty of Health Sciences at the University of Cape Town (HREC REF: 387/2023). A waiver of informed consent was also obtained because data was collected retrospectively. Data was anonymised by allocating participant numbers to each patient in the study to maintain confidentiality. This study followed the principles of the 2013 Declaration of Helsinki.[16]

Results

There were 350 cases of stage IIIB cervical cancer at GSH between January 2017 and December 2018, of which 137 (39%) were staged as IIIB. A total of 132 patients were eligible and included in the final analysis. Five cases were excluded due to bladder involvement ($n = 2$) and patients who relocated elsewhere and did not commence treatment at GSH ($n = 3$).

The mean age of the study population was 52 years (range 24–92, standard deviation 13.2). No statistically significant relation was found between OS and DFS with age and comorbidities. However, there was a statistically significant relation between HIV coinfection and OS ($p = 0.05$) and DFS ($p = 0.03$). The hazard

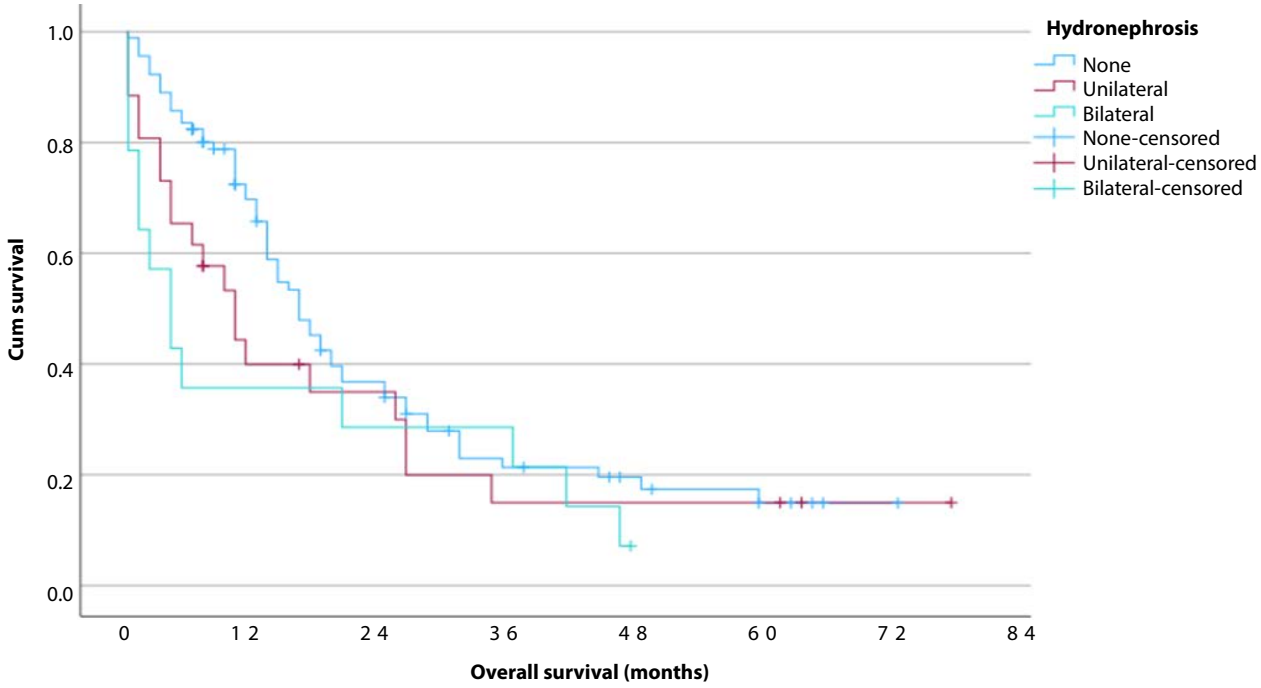

Figure 1: Kaplan–Meier estimate of overall survival according to the hydronephrosis group ($p = 0.16$)

Table I: Relation between overall survival and hydronephrosis

OS	Total	Died	Median overall survival (months)	Cumulative survival at 3 years	Cumulative survival at 5 years
No hydronephrosis	92	63	16	21%	15%
Unilateral hydronephrosis	26	20	10	15%	15%
Bilateral hydronephrosis	14	13	4	21%	7%
Total	**132**	**96**	**15**	**20%**	**14%**

HN – hydronephrosis, OS – overall survival

ratios for OS and DFS were 0.598 (0.357–1.001) and 0.451 (0.218–0.934), respectively. A total of 45 patients (34%) were coinfected with HIV at the time of diagnosis. HIV status did not influence the treatment intent. Patients found to be virally unsuppressed were referred to their local HIV clinic to initiate antiretroviral treatment before commencing CCRT.

Of the 132 patients, 96 (73%) died over five years. The median OS was 15.00 months (95% confidence interval [CI] 11.96 to 18.04). The cumulative survival was 20% at three years and 14% at five years (60 months) after diagnosis. Table I depicts the effect of hydronephrosis on OS. Hydronephrosis did not impact OS: log-rank $\chi 2(2) = 3.66$, $p = 0.16$. There was a trend towards poorer survival in women with bilateral hydronephrosis; however, this was not statistically significant (Figure 1).

There was a tendency to offer radical treatment with CCRT in patients without hydronephrosis, depicted in Table II. Five patients with bilateral hydronephrosis were treated with radical intent; however, only four patients completed treatment. Three patients were referred for percutaneous nephrostomy. Two patients were not offered percutaneous nephrostomy. Reasons included normal renal function and poor performance status.

One patient received CCRT and remains alive with no evidence of disease, while the remaining two received radiotherapy (RT) alone and demised after treatment. The cause of death was attributed to sepsis and progressive disease, respectively. The reason for omitting concurrent chemotherapy was not documented but could be accounted for by a change in treatment protocol at the time.

A total of 82 patients completed radical treatment (CCRT or RT only), of whom 50 (61%) relapsed or died. The median DFS was 13.00 months (95% CI 9.15 to 16.86) in the patient group that

Table II: Treatment modalities split by hydronephrosis

	Type of treatment	Frequency	%
No HN	CCRT (radical)	47	51.1
	RT only (radical)	16	17.4
	Palliation	29	31.5
	Total	**92**	**100**
Unilateral HN	CCRT (radical)	10	38.5
	RT only (radical)	4	15.4
	Palliation	12	46.1
	Total	**26**	**100**
Bilateral HN	CCRT (radical)	2	14.3
	RT only (radical)	3	21.4
	Palliation	9	64.3
	Total	**14**	**100**

HN – hydronephrosis, RT – radiotherapy, CCRT – concurrent chemoradiation

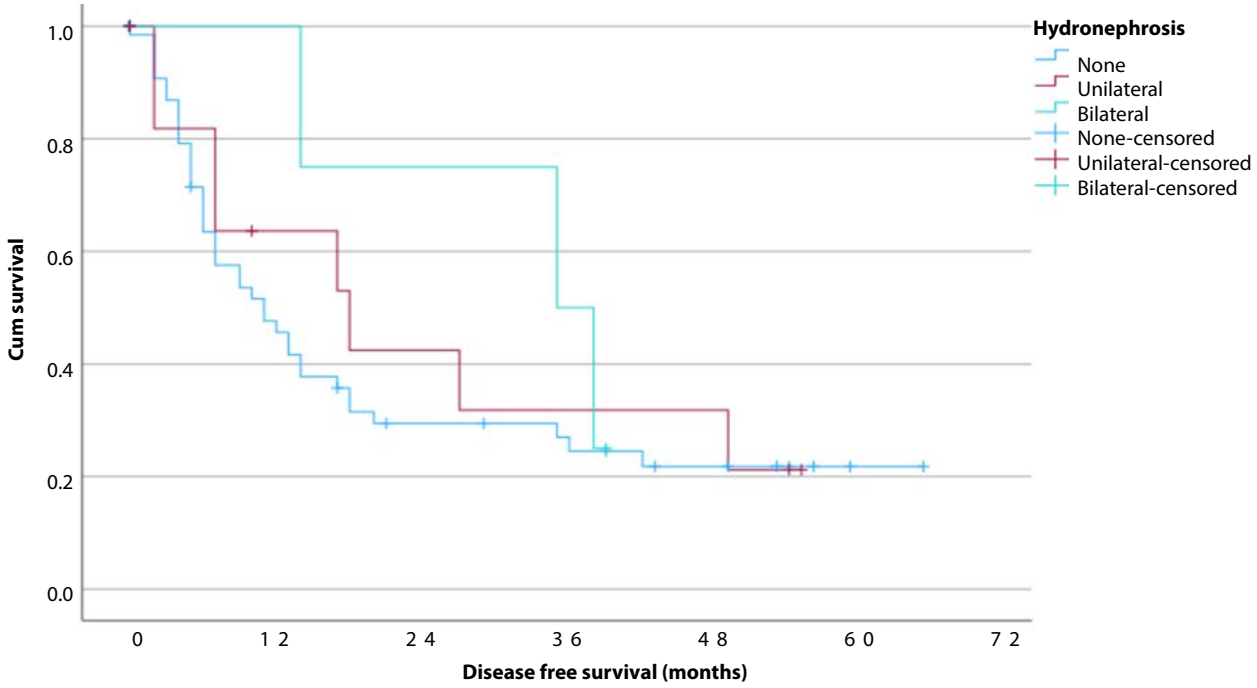

Figure 2: Kaplan–Meier estimate of disease-free survival according to the hydronephrosis group ($p = 0.61$)

Table III: Relation between disease-free survival and hydronephrosis

DFS	Total	Relapsed/died	Median OS (months)	Cumulative DFS at 3 years	Cumulative DFS at 5 years
No HN	65	39	11	25%	22%
Unilateral HN	13	8	18	32%	21%
Bilateral HN	4	3	35	25%	25%
Total	**82**	**50**	**13**	**27%**	**21%**

DFS – disease-free survival, HN – hydronephrosis, OS – overall survival

completed radical treatment. The cumulative DFS was 27% at three years and 21% at five years (60 months) after the first follow-up upon completion of RT. Table III depicts the effect of hydronephrosis on DFS. Hydronephrosis did not impact DFS: log-rank $\chi2(2) = 0.98$, $p = 0.61$ (Figure 2).

Discussion

The high incidence of stage IIIB cervical cancer corroborates much of what has been found at our institution in previous years.[7] Comparative studies, locally and abroad, have not specified the proportion of stage IIIB cancers specifically in relation to all cervical cancer cases; however, they confirm a significantly lower incidence of advanced disease in high-income countries compared to a higher incidence in LMICs.[7,11,17-19] This highlights the disparity between the extent and disease burden in middle- and high-income countries, which often relates to better access to healthcare, screening programmes with interventions, and education. The mean age at diagnosis was 52 years, aligning with studies in the United States of America, Brazil, and South Africa, where the mean age ranged from 49 to 53 .[5,12,20]

While we are aware that there is a higher incidence of cervical cancer among HIV-positive patients, this study also highlights an association between HIV and worse OS and DFS ($p = 0.03$).[5] The study was not powered for this, and the findings require further evaluation. In Botswana, it was found that HIV did not affect OS, whereas a study in South Africa found that HIV-positive cervical cancer patients had a higher all-cause mortality than HIV-negative patients.[21,22] This highlights the importance of voluntary counselling and testing within our communities and ensuring that women are started on and compliant with antiretroviral treatment. Thus, we may be able to reduce the incidence of cervical cancer and improve OS by diagnosing and successfully treating early-stage disease.

A study in India showed a survival benefit in patients who received CCRT compared to RT only; however, this study excluded HIV-positive patients, patients with abnormal renal function, and patients with known para-aortic nodes.[18] We assume that patients with hydronephrosis tend to have worse outcomes following radical treatment. However, our study has demonstrated no statistically significant difference in OS or DFS when comparing patients with and without hydronephrosis. This outcome may be due to our small patient population and the generally high mortality rate for stage IIIB disease, as the surviving fraction of patients with PSW involvement only was 22%. Another consideration may be that these patients could have had undocumented pelvic or para-aortic nodal disease, as the 2009 FIGO staging did not make provision for radiological upstaging for pelvic or para-aortic node involvement. Similar studies carried out in Brazil, Taiwan, Turkey, and the United States of America showed that patients with hydronephrosis had lower OS and progression-free survival than those without

hydronephrosis, identifying hydronephrosis as a negative predictive indicator.[8,12,20,23,24]

Hydronephrosis can be relieved by percutaneous nephrostomy or ureteral stent placement. Percutaneous nephrostomies are the first choice in patients with more severe hydronephrosis, ureteral obstruction > 3 cm in length, or bladder infiltration, as ureteral stent placement has a lower success rate.[10] Our institution follows the same practice of percutaneous nephrostomy over ureteral stent placement in the acute setting. The rationale for this is based on the above reason and financial constraints that encourage cost-saving strategies in our daily practice.

Stents are more expensive, and insertion cannot be justified if the patient deteriorates and is no longer a candidate for radical treatment, nor if the stent migrates while on RT treatment due to tumour response. However, we offer patients stents on follow-up visits if they have ureteric fibrosis or stenosis. Horan et al.[14] recommend careful consideration of candidates who will likely require urinary diversion before starting RT to prevent disruptions and delays during treatment.

Comparative studies abroad showed varying outcomes. Nobrega et al.[12] showed that urinary diversion did not impact OS or progression-free survival. Van Aardt et al.[5] showed an improvement in OS, and Pergialiotis et al.[15] state that it is unclear whether treatment of obstruction may have any benefit. Unfortunately, our study was not powered to determine an association between urinary diversion and treatment outcome.

Palliation, as demonstrated in Table II, included palliative RT and best supportive care. Patients with very advanced or bulky disease, advanced age, or with multiple comorbidities with baseline renal dysfunction were treated with palliative RT. The dose and fractionation depend on the patient's performance status. Patients with a poor performance status were considered for best supportive care, where adequate symptom control and patient and family support are the focus. Locally advanced disease typically has a high symptom burden from diagnosis and often persists during treatment. Radhakrishna challenged our treatment approach to consider a patient-centric one by ensuring the early integration of palliative care combined with radical treatment.[25]

Based on the data of this study, it appears appropriate to adopt this approach to ensure that patients are treated holistically and have the necessary channels of support at their disposal early in their treatment journey, irrespective of their treatment intent. Further consideration can also be given to patient selection for radical treatment, where additional factors like age and disease burden can help steer the decision whether to treat radically or not. Some patients may benefit more from a shorter palliative RT course for local control and improvement in quality of life rather than concurrent RT.

Radiological staging for patients with locally advanced disease may be beneficial in identifying appropriate candidates for radical intent before embarking on treatment, especially when image-guided adaptive brachytherapy is available to ensure that a total dose of 80–90 Gy can be delivered. A higher brachytherapy boost has proven to be a critical component of treatment to maximise the probability of local control and OS.[26] Further studies using a larger cohort and comparing outcomes of patients who underwent urinary diversion followed by definitive chemoradiotherapy are recommended.

Study limitations

A significant limitation of our study is the few patients referred for nephrostomies. Only patients with bilateral hydronephrosis considered for radical treatment were candidates for referral, which excluded 87% of patients upfront. Two of the five eligible candidates were further excluded due to normal renal function and poor performance status. During our study period, we also saw a change in the treatment protocol for stage IIIB patients from RT only to including weekly concurrent cisplatin, which is a confounding factor. Consequently, only one patient referred for nephrostomy received concurrent chemoradiation and, incidentally, is the only patient who remains alive and in remission. This also explains the high rate of patients without hydronephrosis receiving RT only, as depicted in Table II.

The retrospective nature of our study, which was conducted at a single institution, is another limitation. Our study population, specifically patients with bilateral hydronephrosis, was small. Furthermore, many of these patients were not candidates for radical treatment and were not referred for nephrostomies. Our study period saw a change in our radical treatment protocol for stage IIIB from RT only to CCRT, resulting in a treatment plan that was not standardised between patients. Our data looked at patients staged using 2009 FIGO staging, which did not accommodate radiological upstaging and may affect the interpretation of the results.

Conclusion

Hydronephrosis did have a statistically significant impact on OS or DFS. There remains a place for percutaneous nephrostomy in the acute setting, and it is preferred over ureteral stents in a resource-constrained setting, but patient selection and timing are paramount. Further prospective studies comparing the outcomes of patients who underwent urinary diversion followed by definitive chemoradiotherapy are recommended. In our cohort, factors that impacted OS included HIV positivity, but were not significantly linked to hydronephrosis. Further research using a larger patient cohort is recommended to determine if any significant association exists.

Conflict of interest
The authors declare no conflict of interest.

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Ethical approval
Ethical approval was obtained from the Human Research Ethics Committee (reference: 387/2023) before study commencement.

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