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Is young age a risk factor for chronic postoperative inguinal pain after endoscopic totally extraperitoneal (TEP) repair?

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Abstract

Purpose A generally known risk factor for developing chronic postoperative inguinal pain after inguinal hernia repair is young age. However, studies discussing young age as a risk factor are mainly based on open repairs. The aim of this study was to determine if young adults (age 18-30) are also more prone to experience chronic postoperative inguinal pain after totally extraperitoneal (TEP) inguinal hernia repair, compared to older adults (age ≥ 31).

Methods A prospective study was conducted in a high-volume TEP hernia clinic in 919 patients. Patients were assessed using the Numeric (Pain) Rating Scale, Inguinal Pain Questionnaire and Carolina Comfort Scale preoperatively, at 3 months, 1 year and 2 years after TEP mesh repair. The primary outcome was clinically relevant pain in young adults compared to older adults at 3 months follow-up. Secondary outcomes were pain 1 and 2 years postoperatively, the impact of pain on daily living, foreign body feeling and testicular pain. Furthermore, age categories were analyzed to determine potential age-dependent risk factors.

Results Follow-up was completed in 867 patients. No significant difference was found between young adults and older adults for clinically relevant pain at 3 months follow-up (p = 0.723). At all follow-up time points, no significant differences were found for clinically relevant pain, any pain, mean pain scores, the Inguinal Pain Questionnaire and the Carolina Comfort Scale. The subgroup analyses showed no age-dependent risk factor.

Conclusions Young age is not associated with a higher risk of chronic postoperative inguinal pain after endoscopic TEP hernia repair.

Keywords Inguinal hernia · TEP · Chronic pain · Chronic postoperative inguinal pain · Risk factor · Young age

Introduction

Since the introduction of inguinal hernia repair with placement of a mesh, recurrences have decreased impressively [1, 2]. Ever since, chronic postoperative inguinal pain (CPIP) has become the most common disabling complication of inguinal hernia repair [3]. CPIP is defined as inguinal pain lasting more than 3 months after surgery [4, 5]. Various studies report a widespread of CPIP incidence after inguinal

hernia repair ranging from 0.7 to 75% [5]. The reported incidence of CPIP in patients after endoscopic totally extraperitoneal (TEP) repair is 12.4% [6]. Daily activities of patients with CPIP are affected in 2–20% of patients [7]. As summarized in the international guidelines, known risk factors for CPIP are young age, female gender, high preoperative pain level, early high postoperative pain, recurrent hernia and open repair [5]. However, there is no consensus with regard to a definition of 'young age'. Most studies discussing young age as a risk factor for CPIP are based on open repair and relevant studies for endoscopic repair are barely available [7–13]. Since endoscopic TEP hernia repair by experienced surgeons results in a significantly lower incidence of CPIP compared to open repair, it remains unclear if young age is a risk factor for CPIP after endoscopic TEP repair [5].



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The aim of this study was to determine if young adults (18–30 years) are more prone to experience CPIP after TEP repair compared to adults of ≥ 31 years of age.

Methods

Study design

This prospective study was carried out in a high-volume hospital with extensive experience in the endoscopic TEP hernia repair technique (Hernia Clinic Diakonessenhuis Utrecht/Zeist). Hernia repairs were analyzed from the database of a double-blind randomized controlled trial (TULP-trial) comparing lightweight and heavyweight mesh in patients that underwent TEP inguinal hernia repair. Detailed methodology has been published previously [14–17]. Pre- and postoperative data regarding the presence of chronic pain up to 2 years after TEP repair at four time points were prospectively registered. For current analyses, the patients in whom 3 months follow-up (minimum for CPIP) was completed were selected. The patients were included between March 2010 and October 2012. Informed consent was obtained in all patients. The study was approved by the regional Medical Ethics Committee (VCMO, Nieuwegein, The Netherlands) and the local ethics board of the hospital.

Patients

Patients deemed eligible for inclusion were male, over 18 years of age, with a primary, reducible, unilateral inguinal hernia and no contraindications for endoscopic TEP repair. Exclusion criteria were patients with collagen or connective tissue disorders and patients who were unlikely to complete the follow-up regimen since their understanding of the language was insufficient or they had no fixed address.

Intervention

All patients underwent endoscopic TEP repair with tension-free placement of either a lightweight mesh (Ultrapro®, Ethicon, Johnson & Johnson company, Amersfoort, The Netherlands) or a heavyweight mesh (Prolene®, Ethicon, Johnson & Johnson Company, Amersfoort, The Netherlands) (for specifications of mesh, see TULP-trial) [14–17]. Fixation of the mesh was not performed. All procedures were performed under general anesthesia. All patients were operated by four surgeons with extensive experience (> 500 procedures/surgeon) in performing the TEP inguinal hernia repair.



Patients were routinely discharged on the day of surgery, unless complications prohibited early discharge. Patients were advised to take analgesics when in pain, and strenuous physical activity was discouraged during the first week postoperatively. No restrictions were given for activities of daily living.

The primary outcome of this study was clinically relevant pain (NRS 3–10) during rest in 18–30-year-old patients compared to patients ≥ 31 years old at 3 months after endoscopic TEP hernia repair. Secondary outcomes were CPIP (clinically relevant and any pain) during rest, 1 and 2 years after TEP, the impact of pain on daily living, foreign body feeling and testicular pain in young adults compared to older adults. Furthermore, a subgroup analysis of age categories (mostly 10 years per category) was performed to determine a potential age-dependent risk factor for the development of CPIP.

Patients visited the outpatient clinic at 3 months and 1 year for physical examination by a specialized hernia surgeon. Patients were approached by telephone if pain, discomfort or a bulge in the groin was reported in the 2-year questionnaires and offered a clinical appointment if required. Information regarding the, at the time, current presence of pain and the impact on daily living was obtained through questionnaires preoperatively and at 3 months, 1 and 2 years after TEP repair. Pain was measured using the Numeric (Pain) Rating Scale (NRS, a scale of 0 = no pain, 10 = worst imaginable pain, Dutch). NRS scores were reported during rest. Based on a recent systematic review, pain intensity was categorized as mild (NRS 1-2), moderate (NRS 3-6) or severe (NRS 7-10) [18]. Moderate and severe pain (NRS 3-10) were considered clinically relevant. The Dutch versions of the Carolina Comfort Scale (CCS) and Inguinal Pain Questionnaire (IPQ) were used to assess the impact of pain on daily life activities [19, 20]. These are both recommended herniaspecific measurement tools incorporating assessments of both pain intensity and quality of life (QOL) [18]. The CCS is a validated hernia-specific QOL questionnaire with 23 five-point scale questions with 0 being 'no pain, foreign body feeling or mechanical impairment' and 5 being 'terrible pain, foreign body feeling or mechanical impairment' (maximum total of points = 115) [19, 21]. The IPQ uses a seven-step fixed-point rating scale to assess the impact of pain. The questionnaire uses separate questions to report the current inguinal pain, the worst pain experienced during the preceding week and the interference of pain with daily activities. Since the IPQ and the CCS overlap on certain subjects and for the reason of the unpractical extent of



the IPQ questionnaire, the questions regarding a description of the worst pain in the past week, the experience of foreign body feeling (mesh) and pain in the testicle on the operated site were considered most relevant for this study. For the description of the worst pain in the past week, steps 4–7, in which pain cannot be ignored and interferes with daily activities or worse, were considered clinically relevant [20].

Statistical analysis

Sample size calculation and power analysis were performed using R, version 3.5.1 (The R Foundation for Statistical Computing, Vienna, Austria). The hypothesis was that the incidence of clinically relevant chronic pain (proportional outcome) is higher in young adults (18–30 years) than in older adults (> 30 years), as for open repairs and as described in the international guidelines. The analysis was based on the study by Langeveld et al. [22], which is the only other study that analyzes the prognostic value of age for CPIP in TEP (and Lichtenstein) repair patients, and uses a proportional outcome [22]. From the proportions encountered in their study (43.3% in the 18–40 group versus 23.9% in the >40 group), with a two-sided alpha of 0.05 and a power of 0.80, a total of 92 patients were to be included in each allocation group. However, regarding the study design of a secondary analysis of a previously conducted trial, the number of patients analyzed is fixed to 64 patients in the smallest group (age 18-30) and 855 patients in the other group (age > 30). From the study of Langeveld et al. [22], a power of 0.65 was determined for a group n = 64.

Outcome analyses were performed using SPSS statistical software, version 24 (IBM Corp, Armonk, NY). Descriptive

statistics were used for baseline data. The incidence of clinically relevant pain and any pain at the five different time points were compared by means of Chi-square analyses or a Fisher exact test. A univariate analysis was performed for possible confounders (mesh type, BMI, severe preoperative pain, hernia type and operation time). Variables with a p value of < 0.25 in any of the relevant follow-up time points were subsequently entered in a multivariable analysis by means of a binary logistic regression in addition to age of 18–30 years to correct for confounding factors for the association between age of 18–30 years and CPIP experience. The effects of the subgroups of age on clinically relevant pain were described using the relative risk (RR) ratio with the 95% confidence interval (CI). For other endpoints, the Student's t test (normally distributed continuous), Mann–Whitney U analysis (not normally distributed continuous) or Chisquare analysis (categorical variables) was used. A p value of < 0.05 (two sided) was considered significant.

Results

Three-month follow-up in the TULP-trial was completed in 919 patients, with a median age of 55 (IQR 44–64) (Table 1). Follow-up information at 1 and 2 years after TEP repair was available in 894 and 867 patients, respectively (Fig. 1). Significantly more indirect inguinal hernias were seen in young adults compared to older adults (p=0.008). There was no significant difference in mesh distribution (Ultrapro® versus Prolene®) for all age categories.

Clinically relevant pain (NRS 3–10) was present preoperatively, at 3 months, 1 and 2 years in, respectively, 345, 33, 24 and 31 patients. Preoperatively, clinically relevant

Table 1 Patient characteristics

	All patients $(n=919)$	Age $18-30 \ (n=64)$	Age $\ge 31 \ (n = 855)$	p value
Age, years, median (IQR)	55 (44–64)	25 (23–28)	57 (46–64)	
BMI, kg/m ² , mean (SD)	24.9 (2.6)	22.9 (2.3)	25.0 (2.6)	0.000*
Side, <i>n</i> (%)				0.683
Left	394 (42.9)	29 (45.3)	365 (42.7)	
Right	525 (57.1)	35 (54.7)	490 (57.3)	
Hernia type, n (%)				0.008*
Medial	234 (25.5)	6 (9.5)	228 (26.7)	
Lateral	678 (73.9)	57 (90.5)	621 (72.7)	
Femoral	5 (0.5)	0 (0)	5 (0.6)	
Mesh, <i>n</i> (%)				0.734
Ultrapro®	464 (50.5)	31 (48.4)	433 (50.6)	
Prolene®	455 (49.5)	33 (51.6)	422 (49.4)	
Operation time, minutes, median (IQR)	19 (15–23)	20 (17–23)	19 (15–23)	0.496

IQR inter-quartile range, BMI body mass index, SD standard deviation



^{*}p < 0.05

Fig. 1 Flowchart

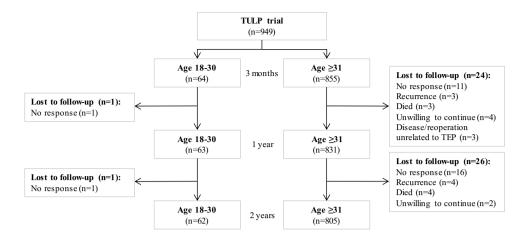


Table 2 Pain results

	Age	p value	
	18–30	≥31	
NRS, mean (SD)		,	
Preoperative	2.53 (2.3)	2.34 (2.4)	0.408
3 months	0.17 (0.5)	0.37 (1.0)	0.145
1 year	0.19 (0.6)	0.24 (0.9)	0.963
2 years	0.21 (0.7)	0.25 (0.8)	0.695
Clinically relevant	pain (NRS 3-10), r	ı (%)	
Preoperative	28 (43.8)	317 (37.1)	0.288
3 months	1 (1.6)	32 (3.7)	0.723
1 year	1 (1.6)	23 (2.8)	1.000
2 years	2 (3.2)	29 (3.6)	1.000
Any pain (NRS 1-	-10), n (%)		
Preoperative	49 (76.6)	604 (70.6)	0.314
3 months	8 (12.5)	168 (19.6)	0.161
1 year	7 (11.1)	93 (11.2)	0.982
2 years	7 (11.3)	105 (13.0)	0.692
Carolina Comfort	Scale ^a , mean points	(SD)	
Preoperative	15.5 (14.5)	14.4 (14.9)	0.396
3 months	4.1 (12.0)	3.0 (8.0)	0.761
1 year	0.9 (3.7)	1.8 (6.1)	0.094
2 years	2.0 (7.1)	1.7 (5.6)	0.652

NRS Numeric Rating Scale, SD standard deviation

pain was present in 43.8% of young adults versus 37.1% of patients \geq 31 years of age. Three months postoperatively, 1.6% of patients 18–30 years of age complained of clinically relevant pain compared to 3.7% of patients \geq 31 years (p=0.723). For the preoperative data and all follow-up time points, no significant difference was found for our secondary outcomes: clinically relevant pain at 1 and 2 years of follow-up, any pain (NRS 1–10), mean pain scores and the CCS (Table 2). Correcting for confounding factors did not change

this finding for both clinically relevant pain and any pain at any of the three follow-up time points (Table 3). A higher BMI, severe preoperative pain and the use of an Ultrapro[®] lightweight mesh remained as independent predictors for clinically relevant pain at 3 months.

Concerning the IPQ question of describing the worst pain in the past week, no significant differences were detected between young and older adults for clinically relevant pain (steps 4–7) both preoperatively and at any time point post-operatively nor were significant differences detected for hindrance of foreign body feeling (mesh) or the experience of pain in the testicle on the operated site.

Analysis of the seven subgroups of age showed that patients 41–51 years old had a significantly higher relative risk (RR) of more clinically relevant pain preoperatively and at 3 months postoperatively compared to the rest of the sample size. One year after TEP repair, this applied to patients 31–40 years of age (Table 4).

Discussion

This prospective study with 2 years of follow-up demonstrates that in a center of expertise, young adults (18–30 years) do not experience more CPIP after TEP hernia repair compared to older adults (\geq 31 years). Moreover, no age-dependent risk factor for the development of CPIP could be identified in our subgroup analysis.

Several studies have shared their findings on the influence of age on CPIP. Nevertheless, up to our knowledge, this is the first study focusing on young age as a risk factor for CPIP after endoscopic inguinal hernia surgery. Our findings of CPIP (NRS 1–10) is 12.5% at 3 months after surgery decreasing to 11.3% over time for age 18-30, and 19.6% decreasing to 13.0% over time for age 18-30, and 19.6% decreasing to 13.0% over time for age 18-30, and 19.6% decreasing to 13.0% over time for age 18-30, and 19.6% decreasing to 18.0% over time for age 18-30, and 19.6% decreasing to 18.0% over time for age 18-30, and 19.6% decreasing to 18.0% over time for age 18-30, and 19.6% decreasing to 18.0% over time for age 18-30, and 19.6% decreasing to 18.0% over time for age 18-30, and 19.6% decreasing to 18.0% over time for age 18-30, and 19.6% decreasing to 18.0% over time for age 18-30, and 19.6% decreasing to 18.0% over time for age 18-30, and 19.6% decreasing to 18.0% over time for age 18-30, and 19.6% decreasing to 18.0% over time for age 18-30, and 19.6% decreasing to 18.0% over time for age 18-30, and 19.6% decreasing to 18.0% over time for age 18-30, and 19.6% decreasing to 18.0% over time for age 18-30, and 19.6% decreasing to 18.0% over time for age 18.0% decreasing to 18.0% over time for age 18.0% decreasing to 18.0% de



^aPreoperative: maximum 75 points; other time points: maximum 115 points

Table 3 Multivariable analysis

	3 months		1 year		2 years				
	OR	CI (95%)	p value	OR	CI (95%)	p value	OR	CI (95%)	p value
Any pain									
Age 18–30	0.66	0.30-1.43	0.293	1.29	0.56-2.99	0.554	0.94	0.41-2.17	0.890
Ultrapro mesh®	0.97	0.70-1.35	0.847	1.05	0.69-1.59	0.835	1.38	0.92-2.07	0.116
BMI	1.06	0.99-1.13	0.085	1.12	1.03-1.21	0.007*	1.04	0.97-1.13	0.286
Severe preoperative pain	1.80	0.81-4.03	0.150	2.54	1.05-6.16	0.038*	1.42	0.53-3.82	0.491
Operation time	0.99	0.97-1.02	0.591	1.01	0.98-1.04	0.703	1.01	0.98-1.04	0.689
Clinically relevant pain									
Age 18–30	0.66	0.09 - 5.03	0.685	0.99	0.12 - 7.88	0.992	1.24	0.27 - 5.62	0.782
Ultrapro mesh®	1.28	0.63 - 2.60	0.501	2.98	1.16-7.65	0.023*	1.97	0.91-4.27	0.087
BMI	1.21	1.07-1.36	0.003*	1.23	1.06-1.42	0.007*	1.09	0.95-1.25	0.227
Severe preoperative pain	2.77	0.78-9.88	0.116	4.12	1.11-15.23	0.034*	6.45	2.23-18.62	0.001*
Operation time	1.00	0.95 - 1.06	0.990	0.99	0.92-1.05	0.686	1.03	0.99-1.08	0.158

All factors were simultaneously entered into the analysis

BMI body mass index

Table 4 Relative risk ratio for experience of clinically relevant pain (NRS 3–10) for different age categories

Age category	Preoperative RR (95% CI)	3 months RR (95% CI)	1 year RR (95% CI)	2 years RR (95% CI)
$18-30 \ (n=64)$	1.18 (0.88–1.58)	0.42 (0.06–3.01)	0.57 (0.08–4.17)	0.90 (0.22–3.67)
31-40 (n=112)	0.97 (0.75-1.26)	1.94 (0.86-4.36)	2.53 (1.03-6.23) ^a	1.53 (0.60-3.88)
41-50 (n=185)	1.24 (1.03-1.49) ^a	2.27 (1.14-4.52) ^a	1.63 (0.69-3.87)	1.62 (0.76-3.45)
51-60 (n=229)	0.84 (0.68-1.03)	0.67 (0.28-1.60)	0.60 (0.21-1.74)	0.58 (0.23-1.49)
61-70 (n=241)	0.95 (0.78-1.15)	0.50 (0.20-1.29)	0.92 (0.37-2.30)	0.94 (0.43-2.07)
71-80 (n=78)	0.92 (0.67-1.26)	0.70 (0.17-2.85)	N/A	0.74 (0.18-3.04)
$\geq 81 \ (n=10)$	1.34 (0.72–2.50)	N/A	N/A	N/A

^aConfidence interval does not include 1.00

One other study by Langeveld et al. [22] had a comparable study design to ours, although patients underwent TEP and Lichtenstein, the sample size was smaller and pain was only assessed as a dichotomous value (yes/no) [22]. They concluded that younger patients (18–40 years) presented more often with CPIP than middle-aged or elderly patients and TEP did not reduce the pain incidence. They, however, neglected to correct for confounders since in their study younger patients also had more frequent preoperative pain and the intensity of pain was higher during the first 3 post-operative days, which are known risk factors for the development of CPIP.

The guidelines defined their statement of young age being a risk factor for CPIP mainly based on studies of patients after open repair [7, 11, 12]. Only two studies investigated pain exclusively after endoscopic repair [9, 10]. Dickinson et al. [9] described a significant correlation of young age and CPIP after TEP; however, young age was defined as <50 years. Lau et al. [10] did not address

chronic pain, but found more acute pain after TEP repair in patients < 65 years of age in the first days after surgery. Liem et al. [8] described a randomized comparison of laparoscopic and open inguinal hernia repairs with 5 years of follow-up. Comparable to our study, age was not identified as a significant influence on the development of CPIP. Only preoperative pain, open repair and an intraoperative lesion of the ilioinguinal nerve were identified as predictors for CPIP.

The subgroup analyses of the current study identified a significantly higher RR for CPIP for the age category 41–50 years, preoperatively and at 3 months. This is most likely due to the aforementioned risk factor preoperative pain and not the age category, especially since significance fades at 1 and 2 years of follow-up. We have difficulty explaining the significantly higher RR seen in patients in age category 31–40 years 1 year after TEP repair, although probably the group sample size and multiple outliers resulted in the outcome.



^{*}p < 0.05

This study did not show more CPIP, foreign body feeling or worse scores concerning QOL in young adults compared to older adults after TEP mesh repair. However, if mesh placement should always be advised in young patients remains questionable. Mesh placement reduces recurrences by reinforcement of the weak inguinal floor. However, in young adults, a different etiology of a patent processus vaginalis might be causative for an indirect inguinal hernia without a weakened posterior wall or large defect [23, 24]. The more frequent appearance is confirmed by both the database of Langeveld et al. [22] and our database that show significantly more indirect inguinal hernias in young adults.

In children (< 18 years), with a patent processus vaginalis as the primary cause of an indirect inguinal hernia, an open herniotomy is the procedure of choice. In patients > 30 years of age with an inguinal hernia, sufficient evidence has been provided that an open herniotomy is accompanied by high recurrence rates which necessitates the use of a mesh [5]. For patients of 18–30 years, the available evidence is weak [5]. A recent retrospective study by van Kerckhoven et al. [25] found recurrence rates after open herniotomy of 0% in patients aged 18–25, 2.7% in patients aged 18–30 years and 4.7% in patients aged 18-40 years, and suggested open herniotomy as a possible treatment of choice in young adults. Osifo and Irowa [26] found one recurrence (0.3%) after open herniotomy in patients with indirect inguinal hernias (mean age 25 ± 5.3 years, range 12–45) with 1–5 years of followup. Well-designed prospective trials with adequate followup duration for the detection of recurrences are lacking and especially in direct inguinal hernias (current study 9.5% of patients) higher recurrence rates are to be expected. In our sample of patients, no recurrences were detected in young adults (age 18-30) after TEP mesh repair with 5 years of follow-up [16].

Therefore, we recommend performing TEP inguinal hernia repair with placement of a mesh in patients of 18–30 years of age. Nevertheless, open herniotomy could be an alternative in young adults who are unwilling to undergo mesh repair. However, higher recurrence rates after open herniotomy are seen and to be expected compared to TEP mesh repair and hence patients should be informed. Randomized controlled trials to detect recurrence differences between TEP and open herniotomy require lengthy follow-up and inordinate sample sizes. Detecting differences in pain might be virtually impossible. Therefore, we see no necessity for randomizing open herniotomy versus endoscopic mesh repair in young adults.

A strength of this study is the long-term follow-up with the use of recommended and validated questionnaires aimed at analyzing (chronic) pain and interference with daily activities [18]. Moreover, the current study provided a fairly pure analysis of the risk factor age. The study design filtered out other risk factors for CPIP development as female gender, recurrences and open repair, and correction for the remaining confounders through a multivariable analysis was performed. Furthermore, the study was conducted in a single, highly experienced TEP center. Comparable to TEP repair, outcomes of chronic pain in young adults after transabdominal preperitoneal (TAPP) repair are underreported. From multiple high-volume comparisons, the recently published international guidelines concluded that TAPP and TEP show similar complication rates for, amongst other outcomes, inguinal nerve lesions, chronic pain and recurrences [5]. Presuming there is no age-related influence on the comparability of TEP and TAPP, extending the current outcomes to laparoendoscopic inguinal hernia repairs seems justified.

A limitation to this study is that it was not primarily aimed at distinguishing between age categories. The original TULP-trial was randomized between lightweight and heavyweight mesh and powered for the detection of pain differences, however, not for age categories resulting in different sample sizes. The sample size of 64 in the age category 18–30 resulted in a power of 0.65, which is below the optimal standard. In a high-volume TEP center, 2.5 years of inclusion yielded 64 patients in this age category. Therefore, achieving a power of > 0.80 will be challenging. Presumably due to the difficulty of establishing sample sizes for optimal power in this age category, this is the first study to analyze patients in the age category 18-30 years after TEP repair. Maintaining prospective inguinal hernia registration databases is advised and might provide adequate sample sizes for analyses of higher power in time. Moreover, since it was not our primary outcome, our subgroup analysis of age categories was not corrected for confounders, including the type of mesh used. Yet, the mesh distribution showed no significant difference for each of the seven subgroups separately in comparison with the rest of the sample population.

In conclusion, age did not prove to be a risk factor for the development of CPIP after TEP mesh repair, which justifies this technique in patients 18–30 years of age.

Author contributions WB: study conception and design, data collection, analysis and interpretation of data, and drafting of manuscript. CH: study conception and design, interpretation of data, and critical revision. EV: study conception and design, and critical revision. GC: study conception and design, and critical revision. PD: study conception and design, and critical revision. NS: data collection and critical revision. JB: study conception and design, drafting of manuscript, interpretation of data, and critical revision.

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Compliance with ethical standards

Conflict of interest Author WB, author CH, author EV, author GC, author PD, author NS, and author JB declare that they have no conflict of interests.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

Ethical standards Ethical approval was obtained by the Regional Medical Ethics Committee and the hospital's Ethics Board.

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