

Randomised clinical trial in umbilical sepsis: A comparative analysis of postoperative outcomes of umbilectomy and umbilicus-retaining procedure

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Abstract. The objective of this study was to analyse the postoperative outcomes between umbilectomy and the umbilicus-retaining procedure in patients presenting with umbilical sepsis. Patients presenting to the surgical clinic with umbilical sepsis were randomised into two groups of 25 patients each based on inclusion and exclusion criteria. Postoperative factors such as pain score, wound infection, recurrence, hospital stay, and cosmetic satisfaction were analysed during follow-up. The parameters observed were statistically analysed using the chi-square test. A p-value of < 0.05 was considered statistically significant. The mean age at surgery in both groups was similar (48 vs. 49, $p = 0.9191$). Based on the pain score after surgery, there is a significant difference ($p = 0.0183$) between the two groups, with higher pain reported in patients undergoing the umbilicus-retaining procedure. Considering wound infection as a parameter, the statistical significance is less ($p = 0.096$). Hospital stay was observed in both groups, and there were no significant differences ($p = 0.7055$). The study population consisted of 23 men and 27 women. Cosmetic satisfaction of patients

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was assessed, and no statistical significance was found ($p = 0.644$) between the two groups, irrespective of gender. Recurrence of symptoms was observed more in the group where the umbilicus is retained ($p = 0.0073$). Considering all the parameters and their statistical significance, it is concluded that postoperative outcomes were comparable in both groups of patients. The results of this study provide insights for surgeons into the concept of retaining or removing the umbilicus and its impact on postoperative morbidity of patients presenting with umbilical sepsis

Keywords: cosmesis; pain scale; recurrence; infection; umbilicus; surgery

◆ INTRODUCTION

The umbilicus is an important aesthetic landmark, marking the waistline, and its absence can result in poor self-image. The aesthetics of the abdomen mainly involve the umbilical scar. The ideal umbilicus should have a natural contour, prominent depth, minimal additional scars, and appropriate superior hooding. Surgical treatment is often preferable to conservative treatment options for many umbilical pathologies, as conservative treatment generally involves a longer healing time and a higher rate of recurrence. By focusing on these aesthetic principles and opting for surgical solutions when appropriate, healthcare providers can better address umbilical issues and enhance both the functional and cosmetic aspects of abdominal health.

K. Perez *et al.* [1] discussed an analysis of 408 patients who underwent umbilectomy and found that umbilectomy significantly decreased the number of patients presenting with wound infection but increased the risk of seroma formation. S.M. Aso *et al.* [2] discussed conservative non-operative management of 114 patients presenting with umbilical pilonidal sinus and found that umbilical preservation is highly possible using an umbilical injection mixture. G. Nisi *et al.* [3] discussed types of umbilical reconstruction techniques and the cosmetic significance of umbilical preservation using U-scoring. A. Sisti *et al.* [4] conducted a literature review on umbilical reconstruction techniques, noted that removal of the umbilicus often becomes inevitable, leaving surgeons in a dilemma whether to retain or remove the umbilicus. M. Gardani *et al.* [5] discuss multiple different options for umbilical reconstruction techniques, which clearly define the difference between umbilical preservation and neoumbilicoplasty. Y.H. Kim *et al.* [6] emphasised the importance of preoperative imaging of patients with umbilical sinus, which aids in the decision-making process regarding the possibility of removing the umbilicus intraoperatively. K. Painter *et al.* [7] highlighted the management of umbilical sepsis and also emphasised wound debridement in a selected group of patients. M. Chua *et al.* [8] discussed the significance of umbilical blood supply in umbilicus preservation techniques, which might produce umbilical necrosis if not done properly.

Literature evidence from many studies lacks clarity on several factors, such as: a) what are the most common postoperative issues patients face after umbilicus surgeries; b) which patients require umbilicus preservation; c) what are the cosmetic aspects of removing the umbilicus for the patient; d) what are the future approaches to treating patients with umbilical sepsis. This study aimed to address all these factors and guide surgeons involved in treating patients with umbilical sepsis. The objective of this study was to analyse the clinical characteristics and postoperative outcomes of umbilectomy versus the umbilicus-retaining procedure in umbilical sepsis.

◆ MATERIALS AND METHODS

This is a prospective, randomised controlled study of postoperative outcomes in patients who underwent umbilectomy versus the umbilicus-retaining procedure for umbilical sepsis. The study included a total of 50 patients who underwent surgery for umbilical sepsis from January 2022 to September 2023 in the Department of General Surgery. The study population comprised 23 male and 27 female patients in total. Group A included 11 male and 14 female patients out of 25, and Group B included 12 male and 13 female patients out of 25. All patient-related demographics were collected while registering the patients for the study. Patients were randomised using a random allocation technique to either group of 25 patients, based on inclusion and exclusion criteria. The random allocation technique was performed by using pre-numbered opaque sealed envelopes sequentially numbered from 1 to 50. Patients were allocated to either Group A or Group B in the same order they were inducted into the study by opening the sealed envelopes. Group A consisted of patients where the umbilicus was removed as part of the surgical incision, and Group B consisted of patients where the umbilicus was retained.

All patients undergoing surgery for umbilical sepsis were elective as well as emergency. Conditions included umbilical sepsis, umbilical pilonidal sinus with abscess, and umbilical granuloma with abscess. Exclusion criteria included patients with uncontrolled diabetes, chronic smokers, morbid obesity, prior laparotomy, and those at extremes of age (paediatric, adolescent, geriatric).

The surgical technique used for both groups was almost similar, except the umbilicus was removed in the umbilectomy group. In Group A where the umbilicus was removed, the abdominal incision was either vertical or horizontal, enclosing the umbilicus all around. The incision was deepened, and the umbilicus along with its stalk, was disconnected from the *linea alba* and excised. Wound debridement was performed. After washing the wound with normal saline, the skin was sutured with non-absorbable sutures and covered with a sterile dressing. In Group B, where the umbilicus was retained, the incision was similar, either vertical or transverse, abutting the umbilicus. The incision was deepened, and infected tissue around the umbilicus was debrided. The wound was washed with saline, and the skin was sutured with non-absorbable sutures.

Patients' follow-up was analysed up to the 6-month postoperative period. Postoperative outcomes such as pain scale, recurrence of symptoms, wound infection, hospital stay, and cosmetic satisfaction were compared between the two groups of patients, and conclusions were drawn based on the statistical significance of these outcomes. Postoperative outcomes were assessed based on standard practices. Pain intensity was assessed using the Universal Pain Assessment Tool (UPAT) [9], which combines

a Visual Analog Scale with a Numerical Rating Scale, a standard pain index scoring method accepted and practised in surgical wards. Pain scoring was recorded on the 3rd and 7th postoperative days, and the average was taken for analysis (Table 1). To reduce the chance of confounding factors such as wound infection or use of painkillers [10],

which can influence pain characterisation, two readings were taken on postoperative day 3 and day 7, and the aggregate was used for analysis. For the postoperative pain grading, the Universal Pain Assessment Tool was used to define the amount of pain experienced by patients in each group (Fig. 1).

Table 1. Universal Pain Assessment Tool (format)

Pain intensity	Scoring	Day 3	Day 7
No pain	0		
Very mild pain	1		
Discomforting pain (Hurts a little bit)	2		
Tolerable pain	3		
Distressing pain (Hurts a little more)	4		
Very distressing pain	5		
Intense pain (Hurts even more)	6		
Very intense pain	7		
Utterly horrible pain (Hurts a whole lot)	8		
Excruciating / Unbearable pain	9		
Unimaginable / Unspeakable pain (Hurts worst)	10		

Source: compiled by the authors

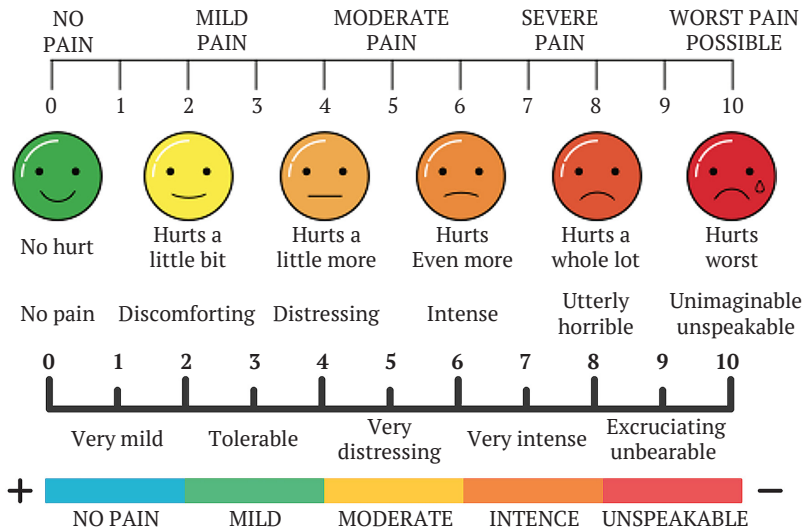


Figure 1. Postoperative pain grading

Source: [9]

Wound infection [11] was assessed by the presence of at least either discharge or slough tissue. A third-generation cephalosporin [12] was the standard antibiotic used for 3 days following surgery for all participants in both groups. Recurrence was assessed at the end of the 6-month postoperative period. Hospital stay was assessed based on the number of days patients were admitted as inpatients. The cosmetic satisfaction questionnaire was given to patients at

the end of 6 months when they returned to the hospital for review, and their opinions were recorded for analysis. This questionnaire was prepared based on inputs from hospital plastic surgery and general surgery consultants and also from a previous similar study [13]. Cosmetic satisfaction was assessed by administering a questionnaire (Table 2) to all 50 patients postoperatively. It is categorised as equivocal (score 1), satisfied (score 2), and highly satisfied (score 3).

Table 2. Cosmetic satisfaction questionnaire (format)

Study Title	Randomised clinical trial in umbilical sepsis: A comparative analysis of postoperative outcomes of umbilectomy and umbilicus-retaining procedure
Patient Name	
IP number	

Continued Table 2.

How satisfied are you cosmetically regarding the wound healing post-surgery?	
Description	✓ Please Tick
Score 1 Equivocal	<input type="checkbox"/>
Score 2 Satisfied	<input type="checkbox"/>
Score 3 Highly satisfied	<input type="checkbox"/>
Kindly give your feedback :	

Source: compiled by the authors

Since the same questionnaire was given to all 50 patients, standardisation of this questionnaire was maintained. The study was conducted taking into account all the ethical concerns as per the hospital’s institutional ethical committee norms. Consent was obtained while registering for the study, which included analysis of collected data from patients. The statistical test used for analysis was the two-way chi-square test. A p-value of <0.05 was considered significant. The study also adhered to the ethical norms of the Declaration of Helsinki [14].

RESULTS

Statistical analysis of various factors was done, which included pain score, wound infection, recurrence of symptoms, hospital stay, cosmetic satisfaction, and conclusions

were drawn. In the umbilectomy group, 15 patients (60%) experienced mild pain (score 2), 8 patients (32%) experienced uncomfortable pain (score 4), and 2 patients (8%) experienced distressing pain (score 6). In the group where the umbilicus was preserved, 10 patients (40%) experienced mild pain (score 2), 12 patients (48%) experienced uncomfortable pain (score 4), and 3 patients (12%) experienced distressing pain (score 6) (Fig. 2). The average pain score was found to be 2.96 in the umbilectomy group, and in the umbilicus-preserving group, it was 3.44. Using the chi-square test, the p-value for the pain factor was found to be 0.0183, and hence pain is considered a significant differentiating factor between the two groups. Pain levels seem higher in patients where the umbilicus is preserved.

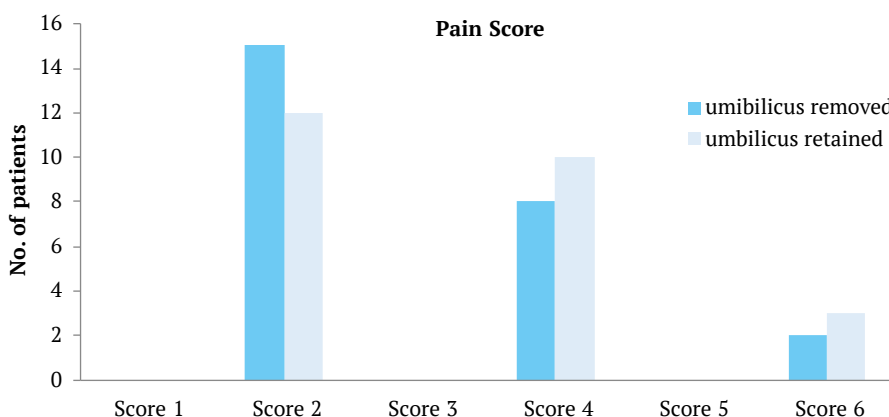


Figure 2. Pain score analysis of both groups

Source: compiled by the authors

Wound infection recorded in both groups of patients was analysed (Fig. 3). In the umbilectomy group, wound infection was noted in 5 patients (20%), and in the group where the umbilicus was preserved, wound infection was noted in 8 patients (32%) (Fig. 3), of which 2 patients developed flap necrosis of the umbilicus. All the patients were conservatively treated except for those with flap necrosis, where minimal debridement was done. The p-value for wound infection between the two groups was found to be 0.096. The statistical significance is less between the two groups, and hence, the groups are comparable.

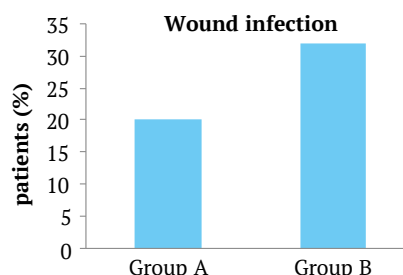


Figure 3. Wound infection in both groups

Source: compiled by the authors

Recurrence of symptoms recorded at the end of 6 months was analysed (Figure 4), and it was found that 1 out of 25 patients (4%) in the umbilicus removal group developed recurrence, whereas, in the group where the umbilicus was preserved, 4 patients (16%) out of 25 had local symptom recurrence (Fig. 4). The p-value for symptom recurrence, using the two-way chi-square test between the two groups, was 0.0073 and is considered statistically significant. Recurrence of symptoms was observed more in the groups where the umbilicus is retained.

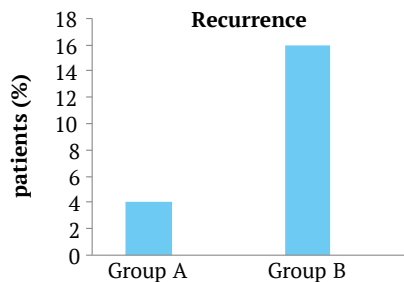


Figure 4. Recurrence in both groups

Source: compiled by the authors

Hospital stay, in terms of the number of days, recorded in both groups of patients was analysed. The average number of days patients stayed in the ward was found to be 3 days in the umbilicus removal group, whereas it was 4 days in the umbilicus preserving group. The p-value concerning hospital stay was found to be 0.7055. Although there is a small apparent advantage for the umbilicus removal group, it is not statistically significant.

15 patients were classified as satisfied, 3 patients were classified as highly satisfied, and 7 patients were classified as equivocal in the umbilicus removal group. In patients where the umbilicus is preserved, 15 patients were classified as satisfied, 4 patients were classified as highly satisfied, and 6 patients were classified as equivocal. The p-value between the two groups, while considering cosmetic satisfaction, was found as 0.644, and hence there is no statistical significance. This factor of cosmetic satisfaction must be interpreted while considering multiple other factors. In this study, we have included both male and female patients. Cosmesis concerning the umbilicus is more important from a feminine point of view. Although statistically this factor is considered non-significant in this study, there is a need for another study involving only females to achieve a proper interpretation of this factor (Table 3).

Table 3. Results with statistical analysis

S. No.	Factors analysed	Group A	Group B	p-value
1	Postoperative pain (Average score)	2.96	3.44	0.0183
2	Wound infection (%)	20%	32%	0.0960
3	Recurrence (%)	4%	16%	0.0073
4	Hospital stay (Days)	3 days	4 days	0.7055
5	Cosmetic satisfaction (Average score)	1.84	1.92	0.6440

Source: compiled by the authors

There were no reported incidences of any major complications related to anaesthesia or surgery, except for a few minor ailments which were not included in this study. Some of the factors noted included minor seroma formation and hematoma formation, which were resolved with routine care. Two patients in Group B, where the umbilicus was retained, also developed scarring that was not considered for analysis.

Postoperative outcomes such as postoperative pain, the incidence of wound infection, and recurrence were found to be comparatively higher in Group B where the umbilicus was retained. Length of hospital stay was only one day more on average in Group B. Cosmetic satisfaction was found to be better in Group B. Statistical analysis showed that postoperative pain and recurrence were higher in Group B.

DISCUSSION

The data collected in this study were compiled and analysed further. Previous studies on similar aspects were taken into account, and results from those studies were also analysed. Although many studies have been conducted on umbilical pathologies, the literature shows only a few studies that did a comparative analysis of postoperative outcomes following the removal and retention of the umbilicus.

Figure 1 shows the Universal Pain Assessment Tool, which is the standard pain scale used in this study. Figure 2 shows that only 8% of patients in Group A and 12% of patients in Group B experienced distressing pain. The majority of patients involved in the study experienced mild to moderate intensity pain (92% in Group A vs 88% in Group B), which indicates that the morbidity of the participants involved in this study is low ($p = 0.0183$). I. Hortu *et al.* [15] used the Numerical Rating Scale to assess the efficacy of postoperative analgesia at the umbilical port site. Numerical Rating Scale values were significantly lower in the study group where local anaesthetic was injected into the surgical wound (median of 2 vs 4; $p < 0.01$). Effective postoperative analgesia encourages early patient mobilisation, which is a basis for the Enhanced Recovery After Surgery (ERAS) protocol. N. Dubey *et al.* [16] used the Visual Analog Scale to compare the pain efficacy following local injection and also classified postoperative complications according to the Clavien-Dindo classification as major, minor, or moderate. Other pain scales in use include the verbal pain scale, verbal rating scale, and generic Linkert scale. The Universal Pain Assessment Tool used in this study effectively incorporates both the Numerical Rating Scale and the Visual Analog Scale.

Figure 3 shows the percentage of patients presenting with wound infection in both groups in this study (20% in Group A vs. 32% in Group B, $p=0.0960$). Wound infection depends on multiple factors, including umbilical hygiene of the patient before surgery, microbial flora status for each patient, prior use of antibiotics, diabetes or other immunodeficiency conditions, and antibiotic preference post-surgery [16]. Third-generation cephalosporins were standard antibiotics used in this study to ensure that wound infection rates remained comparable. Wound infection was comparatively high (32%) in Group B, where the umbilicus was retained and only 20% in the umbilectomy group. Since the primary pathology was umbilical sepsis, the overall incidence of wound infection was high (26%) in this study. K. Tanaka *et al.* [17] discuss the importance of selecting the appropriate antibiotic in patients with umbilical infection and also the high prevalence of multidrug resistance in patients with umbilical infection. Umbilical microflora exhibits a high degree of cephalosporin resistance (46.1%). Coagulase-negative *Staphylococcus aureus* was found to be the most frequent colonising bacteria in the umbilicus. Hence, the choice of antibiotic has been found to influence the incidence of wound infection.

Figure 4 represents the comparison between Group A and Group B concerning the recurrence of symptoms. The recurrence rate was found to be 16% in Group B, which is higher than the 4% in Group A. Patients presenting with recurrence of symptoms were re-evaluated and recommended for an umbilectomy procedure, which was not a part of this study. Overall, 10% of the study population developed recurrence among those who presented with umbilical sepsis ($p=0.0073$). T. Almas *et al.* [18] discussed the importance of preoperative MRI imaging in a selected group of patients to ascertain the depth of umbilical involvement. H. Huang *et al.* [19] discuss preoperative imaging, which provides an idea of the depth of involvement, the involvement of adjacent organs, and the probability of recurrence post-surgery.

Hospital stay was comparable in both groups of patients, measured as the number of days admitted as inpatients (mean days: 3 vs. 4, $p=0.7055$). C.A. Steiner *et al.* [20] assessed the option of hospital-based ambulatory surgery to reduce the number of days of hospital stay, which thereby reduces the cost factors involved in treatment for patients. As hospitals become more capable of handling outpatient surgery, ambulatory surgery or outpatient surgery accounts for a majority of surgeries in recent years, showing an increase in the trend from inpatient care to hospital-based ambulatory surgery (57% in 1994 to 66% in 2014). A comparison of ambulatory surgery with inpatient surgery can provide insights into postoperative complications, length of hospital stay, and hospital cost savings.

Cosmetic satisfaction was assessed at 6 months of age based on a questionnaire-analysed score (mean score: 1.84 vs. 1.92, $p=0.6440$). M.E. Miscia *et al.* [21] assessed cosmetic satisfaction in umbilical incisions and found that transumbilical incision provides better cosmetic results compared to subumbilical incisions, but with a higher incidence of wound infection in the transumbilical incision. Operating time, incidence of granuloma, and surgical site infection were also assessed [15]. J. Raakow *et al.* [22] evaluated

long-term outcomes regarding cosmesis and chronic pain in umbilical surgery using the Patient and Observer Scar Assessment Scale (POSAS). Pain, itching, colour, pliability, thickness of scar, and relief are considered for cosmetic assessment in the POSAS score. Standardised cosmetic evaluations were done based on photographs of the patient's scar by independent surgeons. K.S. Yazar *et al.* [23] used an aesthetic outcome questionnaire given to patients and two independent surgeons to assess the effectiveness of the umbilicoplasty technique.

Overall, all the postoperative outcomes assessed were compiled and subjected to statistical analysis using the two-way chi-square test. Statistical significance was categorised by p-value. Based on the assessment of postoperative outcomes and their statistical significance, conclusions were drawn.

✦ CONCLUSIONS

The primary objective of this study was to compare the postoperative patient outcomes between umbilectomy and umbilicus-retaining procedure for umbilical sepsis. This objective was reasonably achieved based on a carefully designed methodology, the surgical team involved, cooperation from patients, and proper data analysis. The evaluated postoperative outcomes, which have the potential to affect patient morbidity, were chosen based on multiple literature searches conducted prior to the start of this study. In this study, it was observed that the pain factor ($p\text{-value}=0.0183$) and recurrence of symptoms ($p\text{-value}=0.0073$) were comparatively higher in patients where the umbilicus was preserved. Hospital stay ($p\text{-value}=0.7055$), wound infection ($p\text{-value}=0.0960$) and cosmetic satisfaction ($p\text{-value}=0.6440$) were comparable in both groups without any significant difference. Regarding the postoperative pain factor, in the umbilicus-retaining group, the umbilicus was fixed to the *linea alba* with Vicryl, which could have possibly caused increased pain in visual analogue scoring; thus, this statistical difference should be interpreted with caution. Regarding the recurrence of symptoms at the end of 6 months, patient umbilical hygiene post-discharge from the hospital could not be monitored between the two groups of patients, which could have impacted the statistical significance. Hence, in this study, considering the overall perspective authors have concluded that postoperative outcomes were comparable in both groups of patients.

The study is practically significant as it guides clinicians in deciding on umbilectomy in a given scenario. Retaining the umbilicus or removing the umbilicus should be judged based on the individual situation. Factors such as patient symptoms, duration of symptoms, scar, cosmesis, recurrence, emergency or elective settings, and patient preference must be carefully analysed, and a decision should be made accordingly. Future studies with additional parameters, if conducted, could provide more insights into the decision-making process of removing or retaining the umbilicus.

✦ ACKNOWLEDGEMENTS

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✦ CONFLICT OF INTEREST

All authors declare no conflict of interest in this article.

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Рандомізоване клінічне дослідження при пупковому сепсисі: порівняльний аналіз післяопераційних результатів омбілектомії та процедури збереження пупка

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Анотація. Метою цього дослідження було проаналізувати післяопераційні результати між умбілектомією та процедурами збереження пупка у пацієнтів з пупковим сепсисом. Пацієнти, які звернулися до хірургічної клініки з пупковим сепсисом, були випадковим чином розподілені на дві групи по 25 пацієнтів у кожній, відповідно до критеріїв включення та виключення. Післяопераційні фактори, такі як шкала болю, інфекція рани, рецидив, тривалість госпіталізації та косметичне задоволення, були проаналізовані під час подальшого спостереження. Спостережені параметри були статистично проаналізовані. Статистичний аналіз проводився за допомогою тесту χ^2 -квдрат. Значення $p < 0,05$ вважалося статистично значущим. Середній вік на момент операції в обох групах був схожим (48 проти 49, $p = 0,9191$). На основі шкали болю після операції спостерігається суттєва різниця ($p = 0,0183$) між двома групами, де біль виявився більшим у пацієнтів, у яких пупок зберігався. Щодо інфекції рани як параметра, статистична значущість менша ($p = 0,096$). Тривалість госпіталізації в загальному числі днів була спостережена в обох групах, і суттєвих відмінностей не було ($p = 0,7055$). Популяція дослідження складалася з 25 чоловіків і 27 жінок, де косметичне задоволення пацієнтів оцінювалося і не було статистичної значущості ($p = 0,644$) між двома групами, незалежно від статі. Рецидив симптомів спостерігався більше в групі, де пупок зберігався ($p = 0,0073$). Враховуючи всі параметри та їх статистичну значущість, можна зробити висновок, що післяопераційні результати були порівнянні в обох групах пацієнтів. Результати цієї роботи надають хірургам уявлення про концепцію збереження або видалення пупка та його вплив на післяопераційну морбідність пацієнтів з пупковим сепсисом

Ключові слова: косметичний результат; шкала болю; рецидив; інфекція; пупок; хірургія