



Original article

Short-term results of unroofing and marsupialization compared to the Karydakis technique in the treatment of pilonidal sinus. A randomized prospective study



Pedro Antonio Parra Baños,^{a,*} Nuria Martínez Sanz,^a Francisco Miguel González Valverde,^a Jorge Alejandro Benavides Buleje,^a Miguel Ruiz Marín,^a Emilio Peña Ros,^a Carmen Martínez Sanz,^b Mari Fe Candel Arenas^a

^aHospital General Universitario Reina Sofía, Avda. Intendente Jorge Palacios, 1, 30003, Murcia, Spain

^bCentro de Atención Primaria San Andrés, Murcia C/ Escultor Sánchez Lozano, s/n, 30005, Murcia, Spain

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A B S T R A C T

Introduction: The treatment of pilonidal sinus (PS) is usually surgical, but no procedure is considered the *gold standard*. The Karydakis (K) technique is widely used, and unroofing and marsupialization (UM) is a simple surgery with good results.

Primary objective: To evaluate early postoperative complications (EPC) 30 days after UM surgery compared to the K technique.

Secondary objectives: To evaluate surgical time, postoperative pain, patient satisfaction, return to daily activity and early recurrence within 3 months.

Method: Prospective, single-center, randomized study in patients who underwent surgery for primary PS with no abscess between June 2016 and November 2017. They were randomized using a computer-generated block method. To analyze the main objective, a non-inferiority analysis was performed.

Results: 122 patients with symptomatic primary PS were randomized: 60 in the K group and 62 in the UM group. Both groups were homogeneous.

There were statistically significant differences between surgery and postoperative complications at 15 and 30 days in favor of UM. There were also differences in favor of UM in surgical time and return to daily activity. During the 90-day follow-up, there were 3 recurrences in the UM group and 0 in the K group.

Conclusions: UM is a simple, minimally invasive, easily reproducible technique that has a lower rate of early complications, with a shorter operative time and an earlier return to daily activity.

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* Corresponding author.

E-mail address: pedroapb@yahoo.es (P.A. Baños).

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Resultados a corto plazo de la puesta a plano, curetaje y marsupialización frente a la técnica de Karydakis en el tratamiento del seno pilonidal. Estudio prospectivo aleatorizado

RESUMEN

Palabras clave:

Seno pilonidal
Región sacrococcigea
Karydakis
Puesta a plano
Marsupialización
Tratamiento quirúrgico
Complicaciones postoperatorias

Introducción: El tratamiento del sinus pilonidal (SP) es habitualmente quirúrgico, pero no existe un procedimiento considerado como “gold estándar”. La técnica de Karydakis (K) es ampliamente utilizada y la Puesta a Plano, Curetaje y Marsupialización de bordes (PPCYM) es una cirugía sencilla y con buenos resultados.

Objetivo primario: Evaluar las complicaciones postquirúrgicas precoces (CPP) a 30 días tras la cirugía de la PPCYM en comparación con la técnica K.

Objetivos secundarios: Evaluar el tiempo quirúrgico, dolor postoperatorio, satisfacción del paciente, reincorporación a las tareas habituales y recidiva precoz a los 3 meses.

Métodos: Estudio prospectivo, unicéntrico y aleatorizado en pacientes intervenidos de SP primario y sin absceso entre junio de 2016 y noviembre de 2017. Se aleatorizaron mediante un método de bloques balanceados generado por ordenador. Para analizar el objetivo principal se realizó un análisis de no inferioridad.

Resultados: 122 pacientes aleatorizados con SP primario sintomático: 60 en el grupo K y 62 en el grupo PPCYM. Ambos grupos fueron homogéneos.

Hubo diferencias significativas en las complicaciones postoperatorias a los 15 y 30 días a favor de PPCYM. También hubo diferencias a favor de PPCYM en el tiempo quirúrgico y la reincorporación a las tareas habituales. Durante el seguimiento a 90 días hubo 3 recidivas en el grupo PPCYM y 0 en el grupo K.

Conclusiones: UM PPCYM es una técnica sencilla, mínimamente invasiva, fácilmente reproducible y que tiene una menor tasa de complicaciones precoces, con un menor tiempo quirúrgico y una reincorporación a las tareas habituales más precoz.

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Introduction

A pilonidal sinus (PS) is a pseudocyst containing hair follicles, located mainly in the sacrococcygeal region. Diagnosis is based on physical examination and clinical symptoms, which range from mild pain during sitting to an acute abscess with intense pain. Patients often report intermittent suppuration and pain alternating with asymptomatic periods.

Although there are publications that suggest inheritance is an important factor in the genesis of PS,¹ the majority of the scientific community accepts that it is an acquired entity,²⁻⁴ in which hair penetration, favored by microtrauma, occurs in the subcutaneous cellular tissue, causing the formation of the pseudocyst as a result of a reaction to a foreign body. Multiple risk factors have been described that could predispose patients to the appearance of PS: age between 15 and 35 years,³ male sex,⁵ obesity,⁶ hirsutism,⁷ prolonged sitting,¹ etc.

PS affects 26 out of every 100 000 inhabitants in the general population.^{5,8} However, there is a percentage of cases that remain asymptomatic, so it is difficult to establish the real prevalence of PS.⁹

Treatment of symptomatic chronic PS is usually surgical,¹⁰ and numerous techniques have been described that attempt to achieve the *ideal operation* that has low morbidity and recurrence, short hospital stay, good control of postoperative pain, and aesthetically acceptable results. The presentation,

extension and severity are very heterogeneous, so there is no single surgical procedure that can be considered ideal or the *gold standard*.

The Karydakis (K) technique^{11,12} is a standardized procedure that is widely accepted and used by the scientific community.¹³⁻¹⁵ On the other hand, unroofing and marsupialization of margins is a technique described in the 1960s¹⁶ that has been gaining more acceptance in recent decades due to its simplicity and results.^{17,18}

The primary objective of this study is to evaluate the early postoperative complications (EPC) within the first 30 days after unroofing and marsupialization surgery in the surgical treatment of PS compared to the Karydakis technique (K). As secondary objectives, we evaluated the surgical time, postoperative pain, patient satisfaction, return to work or daily activity, healing time and early recurrence within 3 months.

Methods

Patients and study design

A prospective, phase III, single-center, randomized, parallel-group, non-inferiority study was conducted in 122 patients undergoing primary PS surgery at the Reina Sofía Hospital in Murcia, Spain, from June 2016 to

November 2017. The study was conducted in accordance with CONSORT guidelines for randomized studies¹⁸ (Addendum 1).

The study was approved by the hospital's Research Ethics Committee, and all patients signed a consent form for inclusion in the study.

Inclusion and exclusion criteria

Our study included patients of legal age who had been diagnosed with symptomatic primary PS, with no abscess, no pathologies that contraindicated surgery or spinal anesthesia, and who had signed the consent form. Patients with recurrent PS, abscess or episode of inflammation in the previous 4 weeks, PS with bilateral secondary orifices or PS greater than 12 cm and immunosuppressed patients or those with previous radiotherapy on the sacrococcygeal region or who refused to be included were excluded from the study.

Surgical techniques

The surgeries were performed by the same 3 surgeons, under spinal anesthesia, and as part of a day surgery regimen. Patients received a prophylactic dose of IV antibiotic prior to the intervention (2 g of amoxicillin-clavulanic acid or 500 mg of metronidazole +240 mg of gentamicin in patients allergic to beta-lactams). In prone position and with the buttocks separated, patients in group K underwent sinus removal with

a lateralized vertical elliptical excision. A thick flap was created by hollowing out the tissue under the medial side, which is advanced towards the midline to lateralize the entire suture line (Fig. 1).

In the patients of the UM group, the tracts were identified with a stilet, over which an incision was made through the skin, and the PS cavity and its tracts were opened longitudinally, allowing the entire lesion to be flattened out. The hair follicles were then removed, a curettage of the base was performed, and the cutaneous margins were then marsupialized, leaving the wound open to heal by secondary intention (Fig. 2).

Study variables

The study variables collected included sociodemographic data, medical-surgical history, presentation of the disease and evolution over time, treatments received, PS characteristics, and anthropometric data. Intraoperatively, surgical time was measured (from the start of the incision until the last stitch) and postoperatively, wound-related complications during the first month (surgical site infection, suture dehiscence, subcutaneous collections and postoperative bleeding), postoperative pain (using the Visual Analogue Scale), patient satisfaction (using a 5-point Likert scale, where 1 = very bad and 5 = very good), return to normal activities, healing time and recurrence (appearance of new holes accompanied by suppuration or pain) 3 months after surgery.

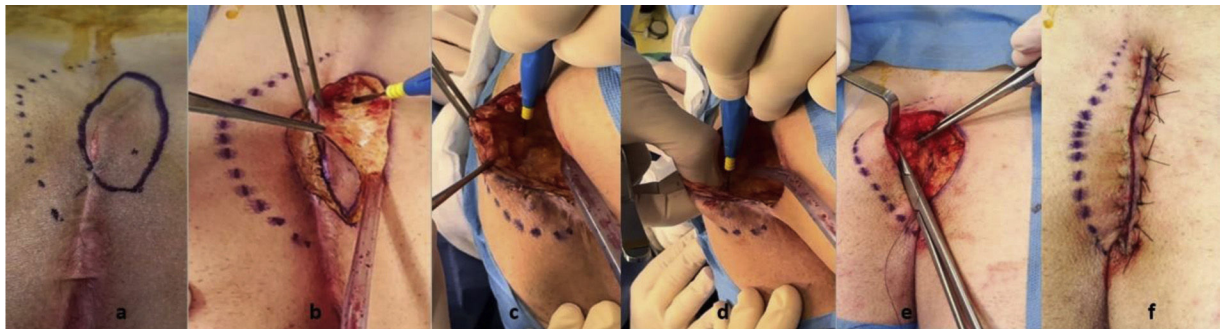


Figure 1 – Diagram of the Karydakis technique: (A and B) lateralized incision; (C and D) preparation of the subcutaneous flap; (E) flap is advanced for suturing; (F) lateral closure at the midline. (Source: our own records).

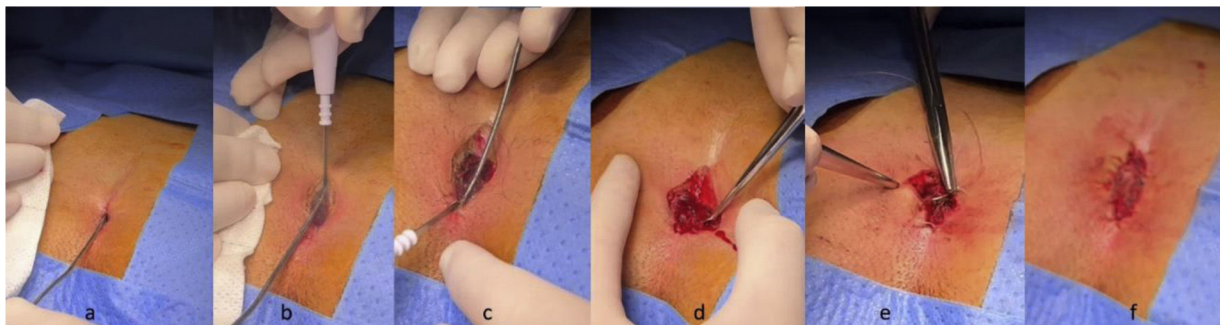


Figure 2 – Diagram of the UM technique: (A) canalization of the tracts with a stilet; (B and C) unroofing and flattening; (D) curettage of the bed; (E) marsupialization of the edges, (F) final appearance. (Source: our own records).

Sample size and randomization

The size of each treatment group was calculated based on the primary endpoint, which was EPC. The percentage of EPC is approximately 9% for the Karydakís technique according to studies by Karydakís¹⁹ and Bannura² and 3% for UM in the study of Karakayali.²⁰

To evaluate the primary objective of the study and declare the non-inferiority of UM compared to K, the lower limit of a two-sided 95% confidence interval for the difference in EPC rates between the experimental group and the reference group needed to be less than 5% (non-inferiority criterion δ).

For a power of 80% and a significance level of 5%, assuming that the proportion of EPC in the reference group (K) is 9% and in the experimental group (UM) 3%, that the proportion of experimental units in the reference group compared to the total is 50% and that the non-inferiority limit is 5%, with an expected dropout rate of 5%, it would be necessary to include 60 subjects in each group, requiring a sample size of 120 patients.

Patients were randomized using a computer-generated balanced block randomization method. The randomization codes were generated by an external computer system, remaining hidden and under the custody of a person outside the study, and only communicated to the surgeons by telephone just before starting the intervention.

Follow-up

After the intervention, the patients were reviewed by a surgeon not involved in the study after 15, 30 and 90 days.

Blinding

The patients, surgeons and outcome assessor could not be blinded to the technique that had been performed. However, the randomization sequence was concealed from the surgeons, and the data were analyzed by another collaborator who was unaware to which group each patient belonged.

Statistical analysis

For qualitative variables, the chi-squared or Fisher test was used. For quantitative variables, the Student's t-test or Mann-Whitney U test was applied.

For the main objective of therapeutic safety, a non-inferiority analysis²⁸ was performed, comparing the percentage of subjects in each treatment group with postoperative complications of the surgical wound during the first 30 days. The non-inferiority analysis for the primary endpoint was conducted using the Farrington-Manning Score, Miettinen-Nurminen Score, and Gart-Nam Score, establishing a significance level of 0.05 and a non-inferiority limit of 0.05.

The primary analysis of the study was based on an intention-to-treat (ITT) analysis of the population.

Data processing and the statistical analysis were performed using the SPSS 22.0 statistical program (IBM® SPSS® Statistics 22) for Windows.

Results

Out of the total of 122 patients, 60 were included in the K group and 62 in the UM group (Fig. 3). The characteristics of the population and PS are shown in Table 1. The groups were homogeneous.

Significant differences were found between surgery and postoperative complications within 15 days (33.3%, 95% CI: 21.4–45.2 in K; and 8.06%, 95% CI: 0.12–14.6 in UM; $P < .001$) but at 30 days (23.3%, 95% CI: 12.6–34.0 in K; and 8.06% 95% CI: 0.12–14.6 in UM; $P = .02$).

Complications in the first 30 postoperative days are shown in Table 2.

All tests performed in the non-inferiority analysis had a P -value $< .05$, and the value 0 was not included in any of the confidence interval limits of all tests. The results of the different variables of the secondary objectives are shown in Table 3.

Operative time was significantly shorter in UM (20.2 min, 95% CI: 19.3–21.16 vs 33.3 min, 95% CI: 31.06–35.54; $P < .001$), while postoperative pain did not show differences between the 2 groups at 15 days but did at 30 days. Patient satisfaction with surgery was very good or good for both techniques, and there were no significant differences between the 2 groups. The mean time until returning to work or daily activities was 17.5 days (95% CI: 15.40–19.60) for UM and 26 days (95% CI: 21.84–30.16) for K, the difference being statistically significant ($P = .01$). Healing was later in UM, but no significant difference was found with K. Three recurrences had been observed within 90 days in the UM group and 0 in the K group.

Discussion

Randomization (controlled for selection bias) has allowed us to study 2 homogeneous groups. Furthermore, despite being limited to a population from a specific health area, the study population is diverse, and we believe that its characteristics can be extrapolated to the general population. UM is a simple technique that could be applied as a surgical option in the vast majority of chronic, symptomatic PS. On the other hand, the study lacks a long follow-up, and, although there have been no losses, it was not possible to evaluate long-term parameters like late complications or recurrences.

PS continues to be a prevalent pathology today with considerable morbidity. As PS is considered an acquired entity, surgical techniques for its treatment tend to be less aggressive and invasive.^{20,21} Some authors claim that radical removal techniques are an "overtreatment" of pilonidal disease²² and suggest techniques such as unroofing, curettage and marsupialization as appropriate therapy for this pathology.

Our overall complication rate with the K technique was 23.3%, which is lower than the rate reported by Alvandipour²³ in 2019 (37 K patients) of 40.85% and higher than the rate reported by Caliskan²⁴ in 2020 (53 K patients) with an early complication rate of 16.9%, but that does not take into account the 5.6% of wound dehiscences included among the late complications. In 2009, the Ersoy study¹³ (50 K patients) reported an infection rate of 26%, much higher than that of

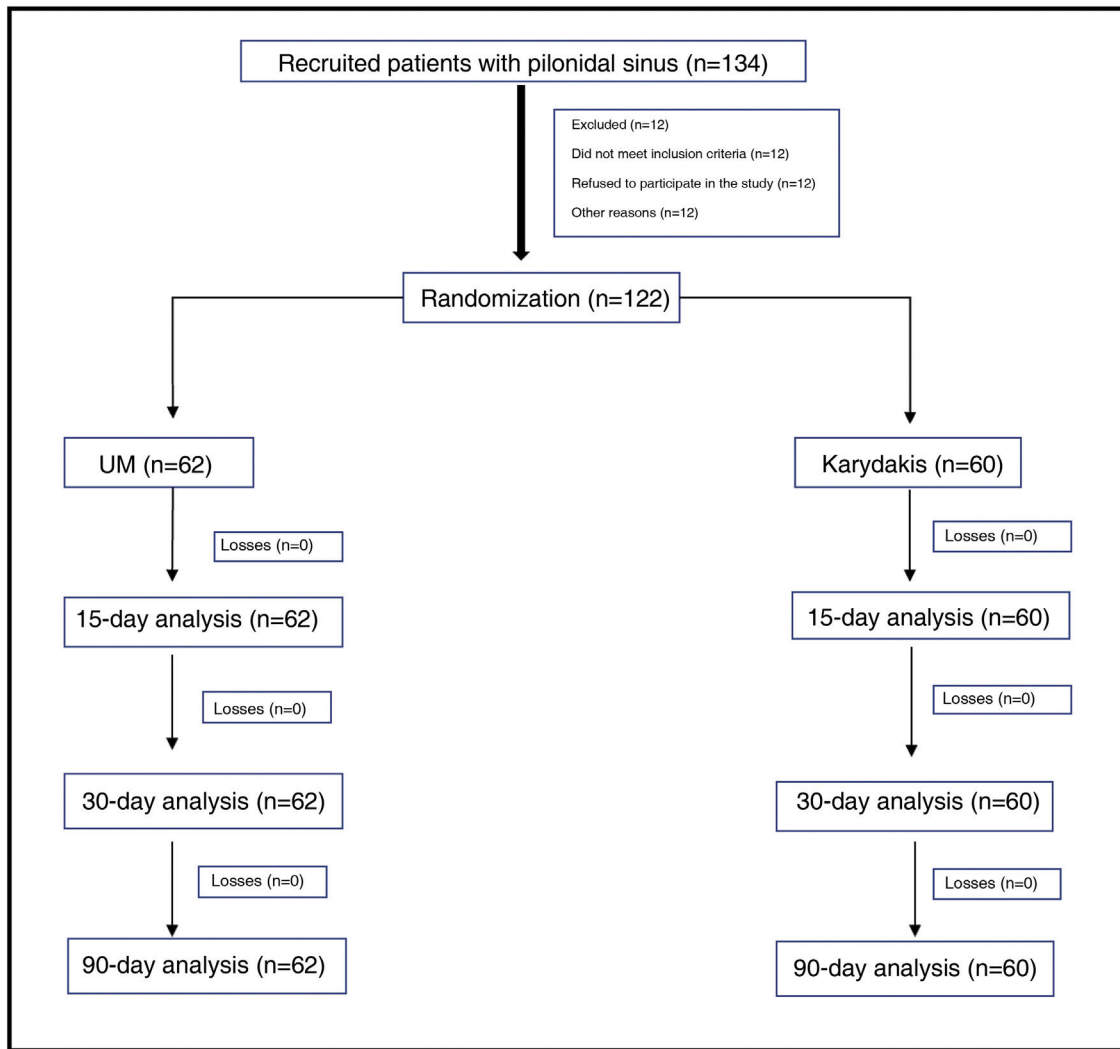


Figure 3 – Flow diagram.

our study at 13.9%. In a 2016 RCT, Keshvari²⁵ (161 K patients) reported an overall complication rate of 18.7%, which was somewhat higher but close to our results.

In the UM group, complications occurred in 8.8%, a higher percentage than that reported in most studies. In a 2005 RCT, Gencosmanoglu²² (73 UM patients) found a complication rate of 2.7%, similar to that found by Karakayali²⁰ in a 2009 RCT (70 patients with UM) of 2.9%. In 2018, Mahran²⁶ reported a complication rate of 6.6% for the UM group (although it only included 15 patients), while in 2013 Goyal²⁷ reported an infection rate of 13% for a group of 15 patients. In our study, one patient in the UM group met the criteria for SSI²⁸ (purulent exudate with + culture and perilesional cellulitis), and another presented dehiscence of the entire suture, thus losing the effect of marsupialization. However, there is a statistically significant difference in favor of the UM patient group.

In our search, we have found no studies of non-inferiority of the UM technique regarding EPC. When comparing this technique with K, the results of all the tests have a *P*-

value $<.05$, so we can conclude that the UM technique is not inferior to the K technique in terms of EPC with a confidence level of 95%.

The operative time is also significantly shorter in UM at 20.2 min in our study, which is similar to the time reported by Mahran²⁶ (22.6 min) and shorter than that reported by Yetisir²⁹ in 2005 (31.5 min). Both techniques are fast, and a difference of 13 minutes does not seem very clinically relevant.

Postoperative pain the first 15 days after surgery did not present differences in the 2 groups, but at 30 days it did in favor of the UM group, although the clinical importance is small. Patients in the UM group were more satisfied with the surgery than those in the K group, although the differences were not significant. These results are similar to those reported by Popesku^{30,32} in 2020.

In our series, the return to work of patients with K was 26 ± 16 days, which is longer than the 11.59 ± 3.4 days reported by Alvandipour²³ and the 14.5 ± 0.67 days of

Table 1 – Characteristics of the patients and sinuses.

Variable	Total	Group		Test	P-value
		UM (n = 62)	K (n = 60)		
Age, mean (SD)	24.5 (9.3)	24.2 (9.3)	24.8 (9.4)	t = -0.35	0.728
Sex, n(%)				$\chi^2 = 0.26$	0.608
Male	82 (67.2)	43 (69.4)	39 (65.0)		
Female	40 (32.8)	19 (30.6)	21 (35.0)		
Body hair, n(%)				$\chi^2 = 1.54$	0.673
No hair	29 (23.8)	15 (24.2)	14 (23.3)		
Mild	32 (26.2)	15 (24.2)	17 (28.3)		
Moderate	42 (34.4)	20 (32.3)	22 (36.7)		
Significant	19 (15.6)	12 (19.4)	7 (11.7)		
Smoker, n(%)				$\chi^2 = 1.60$	0.206
No	62 (50.8)	35 (56.5)	27 (45.0)		
Yes	60 (49.2)	27 (43.5)	33 (55.0)		
BMI (kg/m ²), mean (SD)	24.9 (4.1)	24.9 (4.2)	24.9 (4.1)	t = 0.05	0.959
HTN, n(%)				$\chi^2 = 2.98$	0.084
No	119 (97.5)	59 (95.2)	60 (100)		
Yes	3 (2.5)	3 (4.8)	0		
DM, n (%)				$\chi^2 = 2.98$	0.084
No	119 (97.5)	59 (95.2)	60 (100)		
Yes	3 (2.5)	3 (4.8)	0		
FH, n(%)				$\chi^2 = 2.62$	0.105
No	68 (55.7)	39 (62.9)	29 (48.3)		
Yes	54 (44.3)	23 (37.1)	31 (51.7)		
ASA, n(%)				$\chi^2 = 0.72$	0.699
1	89 (72.9)	47 (75.8)	42 (70.0)		
2	30 (24.6)	14 (22.6)	16 (26.7)		
3	3 (2.5)	1 (1.6)	2 (3.3)		
Initial presentation, n(%)				$\chi^2 = 0.30$	0.862
Local discomfort/mass	42 (34.4)	20 (32.3)	22 (36.7)		
Abscess	68 (55.7)	36 (58.1)	32 (53.3)		
Chronic intermittent discharge	12 (9.8)	6 (9.7)	6 (10.0)		
Drainage, n(%)				$\chi^2 = 0.83$	0.662
No	14 (11.5)	6 (9.7)	8 (13.3)		
Spontaneous	63 (51.6)	31 (50.0)	32 (53.3)		
In the ER	45 (36.9)	25 (40.3)	20 (33.3)		
Evolution (months), mean (SD)	31.0 (48.6)	31.1 (44.6)	31.1 (52.7)	t = 0.01	0.998
N of orifices, mean (SD)	2.4 (1.6)	2.5 (1.7)	2.3 (1.5)	t = 0.69	0.492
Size (cm), mean (SD)	5.09 (1.86)	5.06 (1.87)	5.12 (1.85)	t = -0.187	0.852
Baseline VAS, mean (SD)	2.6 (2.6)	2.5 (2.8)	2.7 (2.5)	t = -0.42	0.678

UM: unroofing and marsupialization; SD: standard deviation; HTN: hypertension; DM: diabetes mellitus; FH: family history; BMI: body mass index; ASA: American Society of Anesthesiologists. VAS: visual analogue scale.

Keshvari,²⁵ although it is closer to the reports by Abellatif³¹ and Tokac³² in 2015, which were 20 ± 6.1 days and 23.29 ± 6.42 days, respectively. In patients with UM, the return to daily activity was 17 ± 8 days after surgery, which was notably higher than the results of Gencosmanoglu²² at 3 (2–8) days or Mahran²⁶ at 3.98 days, yet more similar to those reported by Karakayali²⁰ (11.2 ± 5.8 days) and even lower than the results obtained by Abdeer³³ (25.2 ± 5 days). Despite being an open wound that requires dressings, this earlier return to work could be influenced by less pain in patients with UM and the average size of PS in our series (5.06 ± 1.87 cm), which was not excessively large.

In our series, 3 (4.8%) recurrences occurred within 3 months of follow-up in the UM group, and none were registered in the K group. This figure is higher than in the Gencosmanoglu study²² (1.4% at 47 months) or the Mahran study²⁶ (0 at 6 months) and lower than in the Abdeer study³³ (7% over a 12-

month follow-up). We think that these early recurrences are due to incomplete surgery in which a tract was left unroofed. However, this datum should be measured with a longer follow-up (more than 12 months) to be more reliable.

Conclusions

Unroofing and marsupialization of the margins is a simple, minimally invasive, easily reproducible technique that allows the patient to return to work shortly after surgery. It also has a lower rate of complications compared to the Karydakos technique, requiring less surgical time and causing less postoperative pain, with a similar degree of patient satisfaction. Finally, the population that is most affected is between 15 and 35 years old, hence the growing concern to find a surgery that is minimally invasive, can be performed on an outpatient

Table 2 – Distribution of early postoperative complications (EPC).

Variable	Total	Group		Test (χ^2)	P-value
		UM(62)	K(60)		
Total EPC, n (95% CI)				5.41	0.02
NO	103 (78.28–91.06)	57 (85.1–98.7)	46 (65.91–87.43)		
YES	19 (9.07–21.93)	5 (1.32–14.88)	14 (12.77–33.89)		
Bleeding, n (95% CI)				1.97	0.161
NO	120 (96.11–100.61)	60 (92.38–100)	60 (97.04–100)		
YES	2 (1,6)	2 (0–7.62)	0 (0.11–5.90)		
Collections, n (95% CI)				8.85	0.003
NO	114 (89.06–97.82)	62 (94.1–100)	52 (70.09–95.25)		
YES	8 (2.18–10.94)	0 (0.01–5.82)	8 (4.72–21.94)		
Suture dehiscence, n (95% CI)				9.61	0.002
NO	110 (84.87–95.45)	61 (95.26–100)	49 (81,7)		
YES	12 (4.55–5.13)	1 (0–4.71)	11 (8.53–28.13)		
SSI, n (95% CI)				4.14	0.042
NO	113 (88.1–97.3)	61 (95.26–100)	52 (70.09–95.25)		
YES	9 (2.72–12.04)	1 (0–4.71)	8 (13,3)		

SSI: surgical site infection.

Table 3 – Values of the secondary objectives.

Variable	Total	GROUP		Test	P-value
		UM (n = 62)	K (n = 60)		
Operative time (min), mean (95% CI)	26.7 (25.0–28.4)	20.2 (19.03–21.36)	33.3 (31.06–35.54)	t = -10.35	< 0.001
Postoperative pain (VAS), mean (95% CI)					
15 days	3.49 (3.10–3.88)	3.30 (2.75–3.85)	3.70 (3.17–4.23)	t = -1.027	0.306
30 days	1.42 (1.10–1.74)	0.95 (0.65–1.25)	1.95 (1.39–2.51)	t = -3.102	0.002
Satisfaction, n (%)				$\chi^2 = 8.452$	0.076
1 (very poor)	6 (4.9%)	0	6 (10%)		
2 (poor)	4 (3.3%)	1 (1.61%)	1 (1.6%)		
3 (average)	19 (15.5%)	8 (12.9%)	11 (18.3%)		
4 (good)	30 (24.6%)	15 (24.2%)	15 (25%)		
5 (very good)	63 (51.6%)	38 (61.3%)	27 (45%)		
Return to work/daily activities (days), mean (95% CI)	21.7 (19.34–24.06)	17.5 (15.40–19.60)	26 (21.84–30.16)	t = -3.51	0.001
Healing (days), mean (95% CI)	30.1 (27.12–33.08)	31.5 (28.36–34.64)	21 (15.76–26.24)	t = 0.97	0.333
90-day recurrence, n (95% CI)				Fisher test	0.244
No	119 (94.6–100)	59 (89.9–100)	60 (100)		
Yes	3 (0–5.1)	3 (0–10.1)	0 (0–4.60)		

VAS: visual analogue scale. CI: confidence interval.

basis and allows for faster return to work and daily activities, characteristics that can be attributed to UM. Nevertheless, studies with a larger patient cohort and longer follow-up would be needed to confirm these data and to study other important variables, such as late complications and recurrences.

CRedit authorship contribution statement

Study concept and design: Jorge Alejandro Benavides Buleje, Francisco Miguel. González Valverde and Emilio Peña Ros.

Data collection: Nuria Martínez Sanz.

Data analysis and interpretation: All authors.

Composition and review of the manuscript: Pedro Antonio Parra Baños.

Approval of the final version of the manuscript: All authors.

Agreement to be responsible for all aspects of the study: All authors.

Ethics approval and consent for participation

The study protocol was established in accordance with the ethical guidelines of the Declaration of Helsinki and was approved by the Research Ethics Committee of the Hospital General Universitario Reina Sofía in Murcia, Spain. Informed, written consent was obtained from all participants.

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Declaration of competing interest

The authors declare that this research was conducted in the absence of any commercial or financial relationship that could be interpreted as a potential conflict of interests.

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