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Keystone Versus Rhomboid Flaps in the Management of Sacrococcygeal Pilonidal Disease: A Prospective Randomized Trial in a Tertiary Surgical Center

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Abstract

Background: Surgery for pilonidal disease (PND) entails a variety of procedures with no global consensus regarding the optimal procedure for that entity. Surgeons should seek alternative options to improve patient outcomes. The keystone flap has been applied to cover defects involving the trunk and peripheral limbs, with some evidence of success in PND patients.

Aim and objectives: Herein, we compared the keystone and rhomboid flaps in the management of patients with primary PND.

Patients and methods: This prospective trial included 108 PND patients, who were randomly assigned into two groups: the keystone group and the rhomboid group. The patients were followed for 2 years after the procedure. Operative time and complications, including recurrence, were recorded.

Results: The operative time showed a significant shortening in the keystone approach (52.5 vs. 63.06 min in the rhomboid group). In addition, the keystone patients were able to return to their work earlier than patients in the rhomboid group, although the time needed to walk and sit on the toilet free from pain did not differ between the two groups. The incidence of complications did not differ between the two groups, apart from dehiscence, which was more encountered in the rhomboid approach. Recurrence occurred in 1.9 and 7.4 % of the keystone and rhomboid cases, respectively ($P = 0.169$). Patient satisfaction was significantly better in the keystone group.

Conclusion: The keystone flap has more advantages compared with the rhomboid approach, manifested in a shorter operative time, earlier return to work, and lower incidence of wound dehiscence.

Keywords: Keystone flap, Pilonidal disease, Rhomboid flap

1. Introduction

Pilonidal disease (PND) is a commonly challenging chronic inflammatory disorder that predominantly affects the sacrococcygeal area (the natal cleft).¹ However, it may occur in other anatomical regions, including the neck, axilla, and periumbilical and interphalangeal regions.²

That entity is characterized by entrapment of the hair in the underlying skin and subcutaneous tissue leading to the formation of foreign body granulomatous reaction.³ It affects 26 per 100 000 individuals,⁴ with a high male-to-female ratio (3 : 1).⁵

Its presentation varies widely from asymptomatic painless openings to acute inflammation and abscess formation or chronic inflammation with discharge through the pits.^{6,7}

Numerous surgical modalities are available for the management of PND.^{8,9} The basic principle of any surgical intervention is to remove all sinus tracts,¹⁰ with low recurrence rates, earlier return to work, and accepted cosmetic outcomes.^{11,12} There is a great debate among surgeons regarding the ideal surgical technique for managing PND patients, and that debate could be attributed to the multiple complications after surgery, especially recurrence.¹³

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The keystone flap has been recently described for managing PND with acceptable perioperative and short-term outcomes.^{13,14} It is a perforator-type trapezoid-shaped curvilinear flap that depends on fasciocutaneous or musculocutaneous perforator vessels.¹⁵ It was originally described in 2003 by Behan as a reconstructive technique following skin cancer excision,¹⁶ and its applications have been extended to different anatomical regions, including the trunk and both extremities.^{15,17–19}

The current literature is poor with prospective trials comparing the keystone flap to other conventional flap-based procedures described for PND. That was a strong motive for us to conduct the present trial that aims to compare keystone and rhomboid flaps in the management of nonrecurrent (primary) PND.

2. Patients and methods

The current, randomized, prospective trial was designed for adult patients, whatever their age, diagnosed with sacrococcygeal PND. The patients were collected from the surgical clinic of Al-Azhar University Hospitals, Cairo, Egypt. The study was conducted over a 3-year duration, from August 2020 to August 2023. We started patient enrollment and data collection after gaining approval from the ethics scientific committee of our medical school.

In all, 108 patients were eligible for our study. All patients received the standard preoperative assessment. Moreover, a sinogram was ordered in some cases for delineation of the extension of the sinus tracts. Patients presented with acute abscess, uncontrolled medical comorbidities, recurrent PND, or loss at follow-up were excluded from our study.

After proper patient evaluation, the patients were admitted to the ward the night before the operation. They were asked to shave the hair in the operative area and the nearby perianal region. All patients signed informed written consent after explaining to them the benefits, advantages, and possible complications of each intervention. They were randomly assigned into two groups: the keystone group (54 cases) and the rhomboid group (54 cases). We used the 'sealed envelope' method for the randomization process.

All procedures were performed when the patient was in the prone position, with lateral traction of the buttocks using a wide adhesive tape for better surgical field exposure. The surgical procedures in both groups were performed under spinal anesthesia or saddle block and using complete aseptic precautions.

In the keystone group, we initially marked an elliptical area involving all sinus openings. Lateral

to it, on one side, the keystone flap was marked. We took care that the flap width was identical to the width of the ellipse removed. The flap length was dependent on the length of the elliptical wound. After completing the marking of the skin, we started the operation by the excision of the elliptical area containing the sinus openings, and the dissection was continued down to the presacral fascia. We took care not to leave any tract remnants to decrease the risk of recurrence. Then, good hemostasis was done for the operative bed.

After that, we started the creation of the flap. A skin incision was done over the skin marks without leaving a skin bridge between the flap and the surrounding skin attachments. Our dissection was continued perpendicularly downward to the deep fascia. We did not perform extensive undermining to preserve the vascular integrity of the flap. The flap was then advanced to cover the defect. Deep interrupted Vicryl 0 sutures were used to close the dead space after insertion of a suction drain. Subsequently, the skin was closed using subcuticular Prolene 2/0 sutures, reinforced by interrupted simple sutures to reduce the risk of dehiscence. The donor site was closed in the same manner.

For the rhomboid group, a rhomboid area with upper and lower 60-degree angles and lateral 120-degree angles was marked to involve all sinus openings. An adjacent skin flap was marked as mentioned by Petrucci et al.²⁰ The rhomboid area was excised down to the presacral fascia, followed by good hemostasis of the surgical bed. The flap was then incised and dissected to the deep fascia and then mobilized to cover the defect. Closure of the deep tissues was done by interrupted Vicryl 0 sutures after placement of a suction drain. Then, the skin was closed by subcuticular sutures with reinforcing interrupted ones.

After the procedure, patients in both groups were closely monitored in the surgical ward, and their pain was managed by i.v. ketorolac (30 mg/12 h) and i.v. acetaminophen (1 g/8 h). Most patients were discharged on the first postoperative day on oral medications. All patients were informed to be in a prone or lateral position for at least 2 weeks after the operation.

Follow-up visits were scheduled every week for the first month, and the suction drain was removed if its discharge was less than 20 ml/day and of a serous nature. The stitches were removed after 2–3 weeks. The patients were also asked about the duration elapsed to walking and sitting free from pain and the time to return to work. Any early complications like wound infection or dehiscence were noted and recorded. After 1 month, follow-up

visits were scheduled every 3 months for 2 years, and delayed complications, like seroma and recurrence, were recorded. At the final follow-up visit, the patients were asked to express their satisfaction with the cosmetic outcome of the procedure on a five-degree Likert scale, from very dissatisfied to very satisfied.²¹

The main outcome of our study was the 2-year recurrence rate, while secondary outcomes included the duration of hospitalization and the incidence of other postoperative complications.

2.1. Sample size calculation and statistical analysis

The proper sample size was estimated using on-line software (Cliniccalc.com). As reported in the previous study published by Roatis and Georgescu,¹⁴ the incidence of recurrence was 0 % in the keystone group and 13.33 % in the rhomboid group. We needed a sample size of 108 patients (54 patients in each group) to achieve a 0.05 significance level and 80 % study power.

We used the SPSS software for MacOS (version 26.0; SPSS Inc., Chicago, Illinois, USA) for data tabulation and analysis. χ^2 test was used to evaluate categorical variables between the groups after they had been expressed as frequencies and percentages. Skewed numerical variables were expressed in medians and ranges and compared between the two groups using the Mann–Whitney test, while non-skewed variables were expressed as means and SDs and compared between the two groups using Student's *t*-test. A *P* value less than 0.05 was considered significant for any of the previously mentioned tests.

3. Results

Demographic details of the cases that were included, as displayed in [Table 1](#), did not significantly differ between the two groups. The mean age of the patients in the keystone group was 31.22

Table 1. Basic demographic data of the study cases.

	Keystone group (N = 54) [n (%)]	Rhomboid group (N = 54) [n (%)]	<i>P</i> value
Age (years)	31.22 ± 8.40	33.39 ± 8.28	0.180
Sex			
Male	47 (87.04)	45 (83.33)	0.588
Female	7 (12.96)	9 (16.67)	
BMI (kg/m ²)	30.78 ± 4.38	31.06 ± 3.91	0.727
Comorbidities			
Diabetes	2 (3.7)	2 (3.7)	1
Hypertension	3 (5.56)	2 (3.7)	0.647
Smoking	6 (11.11)	8 (14.81)	0.567

years, whereas it was 33.39 years for the rhomboid group. Men made up the majority of participants, making up 87.04 and 83.33 % of the cases in the same two groups, respectively. In the same groups, their BMI had mean values of 30.78 and 31.06 kg/m², respectively. Statistics showed that our two groups' rates of smoking, diabetes, and hypertension were comparable.

All patients presented with discharge. Other complaints included pruritus, pain, and bleeding. The duration of these manifestations had median values of 12 and 11 months in the keystone and rhomboid groups, respectively. Previous abscess drainage was reported in 12.96 % of the keystone cases and 16.67 % of the rhomboid cases. The number of midline openings ranged between 2 and 5, whereas the number of lateral pits ranged between 0 and 3 in both study groups. All previous parameters showed no significant difference between the two groups ([Table 2](#)).

The operative time showed a significant shortening in association with the keystone approach (52.5 vs. 63.06 min in the rhomboid approach). Nonetheless, the duration of hospitalization was statistically comparable between the same groups (*P* = 0.2) ([Table 3](#)).

Regarding postoperative recovery, the two groups showed no significant difference regarding the time needed to walk or sit on the toilet free from pain (*P* = 0.813 and 0.215, respectively). The time to return to daily activities had a median value of 19 days in the keystone group, which was significantly earlier than the rhomboid group (median = 22 days) ([Table 4](#)).

Table 2. Clinical presentation and examination findings of the study cases.

	Keystone group (N = 54) [n (%)]	Rhomboid group (N = 54) [n (%)]	<i>P</i> value
Presentation			
Discharge	54 (100)	54 (100)	1
Pruritus	22 (40.74)	19 (35.19)	0.552
Pain	11 (20.37)	13 (24.07)	0.643
Bleeding	2 (3.7)	2 (3.7)	1
Duration of symptoms (months)	12 (6–18)	11 (6–17)	0.660
Previous abscess drainage	7 (12.96)	9 (16.67)	0.588
Number of midline openings	3 (2–5)	4 (2–5)	0.628
Number of lateral openings	1 (0–3)	2 (0–3)	0.765

Table 3. Operative time and the duration of hospitalization of the study cases.

	Keystone group (N = 54)	Rhomboid group (N = 54)	P value
Operative time (min)	52.50 ± 7.99	63.06 ± 10.21	<0.001
Hospital stay (h)	19.19 ± 1.81	18.74 ± 1.77	0.200

Table 4. Postoperative recovery data in the two groups.

	Keystone group (N = 54)	Rhomboid group (N = 54)	P value
Time to walk pain-free (days)	8 (6–9)	8 (7–10)	0.813
Time to sit on toilet pain-free (days)	12 (9–13)	11 (10–14)	0.215
Time to return to work (days)	19 (17–21)	22 (19–25)	<0.001

The incidence of postoperative complications, including wound infection and seroma, did not significantly differ between the two groups. Nonetheless, the incidence of wound dehiscence was significantly higher in the rhomboid group (25.93 vs. 1.9 % in the keystone group). No patients developed hematoma of flap necrosis in our study. At 2-year follow-up, recurrence was detected in 1.9 and 7.4 % of keystone and rhomboid cases, respectively ($P = 0.169$) (Table 5 and Fig. 1).

Patient satisfaction with their cosmetic outcome was significantly better in the keystone group (Table 6 and Fig. 2).

4. Discussion

The success of the surgical treatment for PND is determined by shorter operative time, shorter hospital stay, fewer complications, low recurrence rates, and earlier return to work and daily activities.^{22,23} Although many surgical options exist for PND, most of them fail to meet all the previous parameters.

Table 5. Incidence of postoperative complications in the two groups.

	Keystone group (N = 54) [n (%)]	Rhomboid group (N = 54) [n (%)]	P value
Wound infection	3 (5.56)	6 (11.11)	0.296
Wound dehiscence	1 (1.9)	14 (25.93)	<0.001
Flap necrosis	0	0	NA
Hematoma	0	0	NA
Seroma	2 (3.7)	2 (3.7)	1
Recurrence after 2 years	1 (1.9)	4 (7.4)	0.169

Therefore, general surgeons must seek alternative options to enhance patient outcomes.

Herein, we compared the keystone flap, which is a relatively new procedure described for PND management, with the rhomboid flap, which is more commonly performed in our Egyptian surgical setting. We prefer to perform flap-based procedures to create a tension-free incision and to create a scar away from the midline. That should theoretically decrease the risk of complications, especially dehiscence, and recurrence, compared with direct closure approaches.¹⁷ The rhomboid flap has become popular in the Egyptian setting because of its good outcomes and low recurrence rate.^{24,25}

First off, there were no discernible differences between our two groups' preoperative demographic and clinical parameters for the reader to detect.

We noted a significant shortening in the operative time in association with the keystone technique. Other studies confirmed our findings regarding the operative time. Roatis and Georgescu¹⁴ reported that patients in the keystone group had a mean operative time of 33.86 min compared with 41.26 min in the rhomboid group ($P = 0.001$).

In our study, the surgical approach did not have a significant impact on the hospitalization period, as our center protocol is to discharge the patient within 24 h after the operation unless complications were encountered. Another study reported a shorter hospitalization period in the keystone group (2.33 vs. 4 days in the rhomboid group – $P = 0.003$).¹⁴

Regarding postoperative recovery, our findings are in favor of keystone patients, who were able to return to their work earlier than patients in the rhomboid group. Although our findings did not show a statistical difference regarding the time to walk and sit on the toilet, the reported range was shorter in the keystone group. That could be explained by less extensive tissue mobilization in the keystone group, which decreases the impact of surgical trauma, leading to a better recovery profile. This is in accordance with the findings of Roatis and Georgescu,¹⁴ who reported that the keystone approach was associated with earlier time to walk pain-free (9.06 vs. 9.6 days in the rhomboid approach), earlier time to sit on the toilet pain-free (10.26 vs. 11.8 days in the other group), and earlier return to work (21.93 vs. 23.4 days in the other group).

In the current trial, superficial wound infection occurred in 5.56 and 11.11 % of cases in the keystone and rhomboid groups, respectively. The incidence in our two groups lies within the incidence reported in the literature for the same complication after surgery for PND, which ranges between 6 and 14 %.²⁶

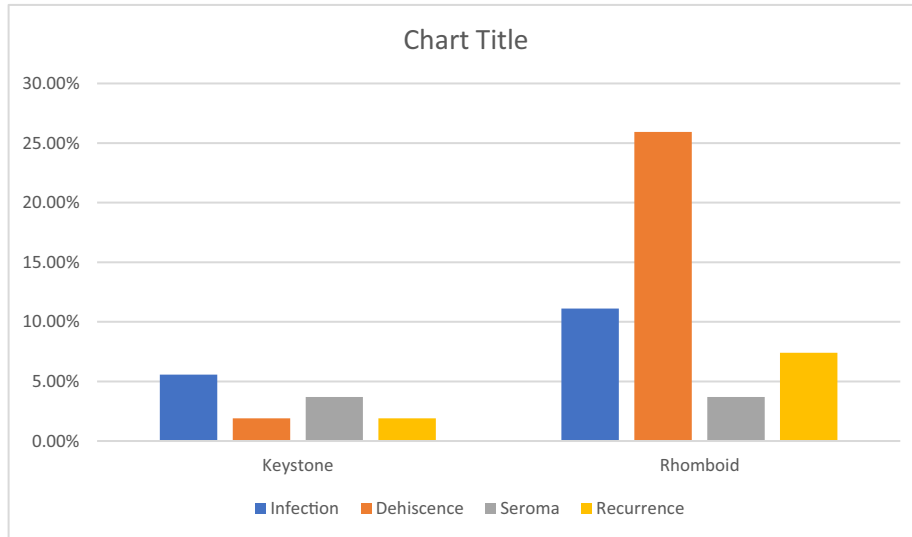


Fig. 1. Complications in the two groups.

Table 6. Patient satisfaction with their cosmetic outcomes in the two groups.

	Keystone group (N = 54) [n (%)]	Rhomboid group (N = 54) [n (%)]	P value
Very satisfied	20 (37.04)	9 (16.67)	<0.001
Satisfied	18 (33.33)	7 (12.96)	
Neutral	11 (20.37)	14 (25.93)	
Unsatisfied	3 (5.56)	14 (25.93)	
Very unsatisfied	2 (3.7)	10 (18.52)	

Our findings showed a decreased incidence of wound dehiscence in association with the keystone flap procedure. The flap itself entails the formation of two V–Y islands that decrease the longitudinal tension.¹⁶ This, in turn, facilitates the healing

process and decreases the risk of dehiscence.^{27,28} The keystone flap is characterized by the preservation of perforator vessels, which preserve the viability of the flap and enhance wound healing.¹⁵ In agreement with the previous findings, another study reported an incidence of 23.9 % for the same complication after the rhomboid flap, compared with 9.4 % after the keystone flap ($P = 0.03$).¹³

In our study, postoperative seroma occurred in two cases in each group (3.7 %). This lies within the range reported in the literature for the occurrence of seroma following flap-based procedures for PND, which ranges between 0 and 14.5 %.^{29–31}

Our incidence of recurrence is in accordance with the literature that may reach up to 9 % for flap-based procedures in PND patients.³² In previous

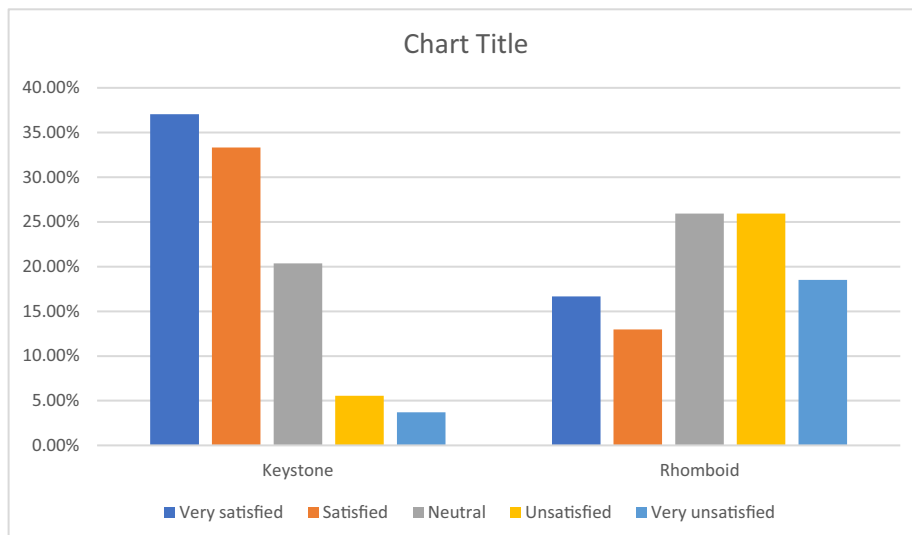


Fig. 2. Patient satisfaction.

similar studies, other authors reported recurrence rates of 0 and 13.33 % 1 year after the keystone and rhomboid flaps, respectively.¹⁴ In addition, Calisir and Ece¹³ reported that the same complication was encountered in 1.9 and 2.8 % of cases after the same two approaches, respectively ($P = 0.73$) (mean follow-up period = 17.6 months).

The findings of our trial showed better patient satisfaction regarding the cosmetic outcome of the surgical procedure in association with the keystone approach ($P < 0.001$). The increased incidence of cutaneous complications like dehiscence and infection in the rhomboid group could explain these outcomes.

Our study discussed a unique surgical topic. Nonetheless, it has some limitations. The relatively small patient sample, which was collected from a single surgical center, is the main limitation. The lack of long-term follow-up is another one. More trials should be conducted to address the previous limitations.

4.1. Conclusion

Both keystone and rhomboid flaps are good options for the management of PND with comparable recurrence rates. However, the keystone flap has more advantages compared with the rhomboid approach, manifested in shorter operative time, earlier return to work, and lower incidence of wound dehiscence. These results should not be generalized till performing more studies, including more cases or meta-analyses to elucidate which is the best technique for managing PND.

Conflicts of interest

There are no conflicts of interest.

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