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BREAST SURGERY

Central mammary duct excision – a randomised controlled study between two different surgical techniques

MA Alhussini,[1] MS Foula,[2] H Fayed,[1] AM Eldamati[1]

[1] *Surgical Oncology Unit, Faculty of Medicine, Alexandria University, Egypt*
[2] *Imam Abdelrahman Bin Faisal University, Saudi Arabia*

Corresponding author, email: *mahmoud.elhussini@alexmed.edu.eg*

Background: Since the 1960s, mammary duct ectasia (MDE) has been surgically treated by the Hadfield technique. After 1999, the Al-Masad technique was developed to overcome the adverse events related to the former technique. However, literature comparing both techniques is still deficient. The purpose of this study was to compare both techniques in terms of nipple sensation, recurrence of symptoms, nipple-areola complex (NAC) necrosis, nipple retraction and any other complications.
Methods: This prospective randomised clinical trial was performed at the Alexandria Main University Hospital, Egypt, and included consecutive patients with mammary duct ectasia who were randomly assigned into two groups – group A who were treated using the Al-Masad technique, and group B who were treated using the Hadfield technique.
Results: The study included 130 patients (group A = 65 patients and group B = 65 patients) with a mean age of 51.42 ± 5.1 years ($p = 0.564$). Most lesions were unilateral in both groups (76.9% vs 83.1%; $p = 0.38$). The main indication for surgery was significant copious discharge in both groups (61.5% vs 52.3%; $p = 0.56$). Intraoperative details were comparable between both groups. The main pathological finding was duct ectasia with and without periductal mastitis (46.2% vs 52.3%; $p = 0.78$). Both groups had a comparable incidence of postoperative complications, except nipple retraction, which had a higher frequency among group B (2.5% vs 15.8%; $\mathbf{p = 0.004}$).
Conclusion: The Al-Masad technique was as effective as the Hadfield technique in treating mammary duct ectasia with lower postoperative complications, especially nipple retraction.
Keywords: mammary duct ectasia; mammary duct excision; nipple retraction.

Introduction

Mammary duct ectasia (MDE), first described in the early 1950s, is a common clinical entity with a significant negative impact on the quality of life of patients. It is a benign non-proliferative disease affecting one or both breasts of peri-menopausal females with a rare occurrence in males.[1,2]

The underlying pathogenesis of MDE is not well known and multiple risk factors have been suggested.[1,3] Its clinical presentation varies from asymptomatic to nipple discharge, mastalgia, palpable tender masses, chronic abscesses, fistula and/or nipple retraction.[1-3]

The character of the nipple discharge is diverse – whitish, yellowish, greenish or blood-stained. Malignancy should be excluded in cases of blood-stained discharge, especially with palpable masses.[1,2]

Management of MDE depends mainly upon the symptoms of the patients. Mild cases require assurance and/or conservative management in the form of antibiotics. However, severe cases typically require surgical excision of central mammary ducts.[1]

In 1960, Hadfield described the Adair and Urban technique for benign mammary duct excision, which remains the standard technique to date.[4] It involves an infra-areolar incision and excision of the central mammary ducts. However, it is associated with several complications, including loss of nipple sensation, nipple-areola complex (NAC) necrosis, nipple retraction, postoperative infection, and recurrence.[5] The site of incision is thought to be the reason for complications; therefore, several modifications have been described, including radial incision, round block incision and combined radial and peri-areolar incision.[5-8]

Based on different anatomical studies, in 1999 Al-Masad described a new technique for mammary duct excision that avoids the complications of the classical Hadfield procedure.[6] His operative technique composed of a supra-areolar incision, closure of the dead space, de-epithelised crescent-shaped skin, and advancement flap of the NAC cranially.

He believed that his technique would avoid injury of the main sensory supply to the areola from the inferolateral aspect and would offer support to the nipple, preventing its retraction.[6]

The literature lacks well-designed prospective studies that compare the classical Hadfield procedure and Al-Masad technique for mammary duct excision. We aimed to prospectively compare both techniques in terms of nipple sensation, recurrence of symptoms, NAC necrosis, nipple retraction and other complications.

Methods

This was a prospective randomised trial that included all consecutive patients who underwent mammary duct excision in a tertiary university institute (Alexandria Main University Hospital) from November 2019 to July 2022.

The trial was registered in the clinical trials registry (NCT04744766)

Randomisation

All patients with non-malignant bleeding per nipple, copious nipple discharge and/or recurrent peri-ductal mastitis were enrolled and randomly divided into two equal groups, using the closed envelope technique. The first group (group A) underwent mammary duct excision using the Al-Masad modified technique while the second group (group B) underwent mammary duct excision using the classical Hadfield technique (Figure 1).

Exclusion criteria

Patients with preoperative nipple retraction, malignant breast lesions and those with a postoperative diagnosis of malignancy were excluded.

Objectives

The primary objective was to assess the postoperative tactile nipple sensation, which was assessed by a nurse (blinded to the study design) during the follow-up visits (ten days, six and 12 months postoperatively) using a cotton earbud in comparison to the other side or the nearby skin, in cases of bilateral disease. The secondary objective was to assess other complications, including symptoms of recurrence, nipple retraction, NAC necrosis and infection.

Hypothesis and sample size

We hypothesised that impaired areola sensation would be found in 100% of patients in the classical Hadfield technique compared to only 50% in patients after the Al-Masad modified technique within three months of surgery. The hazard ratio (HR) was calculated to be 0.5. We used an unstratified log-rank test with a two-sided 5% significance level, a power of 80%, and a 1:1 ratio to calculate the sample size. A total sample size of 132 patients was needed, 66 patients in each group.

Steps and procedure

All included patients signed an informed consent and were subjected to a thorough clinical examination, breast ultrasonography and/or mammogram. Image-guided biopsy was performed for any suspected breast lesion. Cytological examination was only performed for patients with bloody nipple discharge.

All procedures were performed under general anaesthesia. A circum-areolar incision was performed ranging from 1/3 to 1/2 of the areola, either in the upper half of the nipple in group A or the lower half in group B.

In both groups, the areola flap was sharply dissected, using scissors, with a flap thickness of 2–3 mm to prevent ischemic insult to the flap.

Central ducts were dissected, skeletonised from all tissues, clamped by a haemostat, ligated with 2/0 silk or polyglycolic sutures, if required, and then sharply cut while inverting the nipple with the index finger of the other hand to ensure

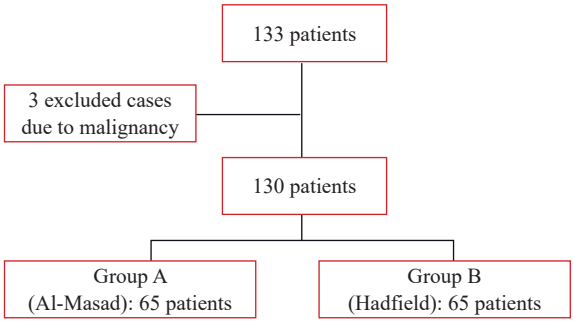

Figure 1: CONSORT flow diagram of the study

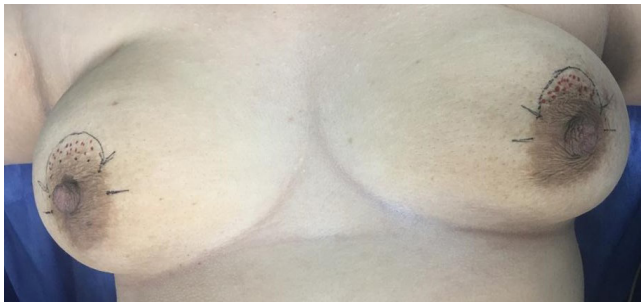

Figure 2: A case of bilateral duct ectasia with skin markings of the supra-areolar area to be de-epithelialised using the Al-Masad technique

transection of the entire ductal system to avoid recurrence of the symptoms. A cone of breast tissue, with epicentre over the dissected ducts, was removed according to the extent of the disease. The dead space was obliterated, using 3/0 absorbable sutures, after irrigation with povidone-iodine and ensuring good haemostasis. A narrow-calibre tube drain (8 Fr) was inserted in some patients at one end of the incision, draining into a dressing.

In group A, a crescent-shaped skin area just above the incision was de-epithelised to create a bed for the upper half of the areola flap (Figures 2 and 3) which was advanced and sutured all around. In both groups, the skin was sutured using 4/0 non-absorbable polypropylene sutures.

Antibiotic policy

All patients received a single dose of intravenous antibiotics (amoxycillin 1 g and clavulanic acid 200 mg) upon induction of the general anaesthesia then continued orally for seven days. Extended antibiotic coverage is aligned to our institution's antibiotic policy, which includes older patients (> 45 years), duct contents exposure (bacterial colonisation risk) and the presence of a drain for 48–72 hours postoperatively.

Hospital stay and follow-up

All patients were discharged on the same day and recalled after 48–72 hours to remove the drain if used. All patients were followed up in the outpatient clinic after ten days for removal of sutures and assessment of early results. They were recalled at six and 12 months for reassessment.

Statistical analysis

The collected data was analysed using the 20th version of the Statistical Package for Social Science (Armonk, NY: IBM Corp). The qualitative data was presented as numbers and percentages, and the quantitative data with parametric

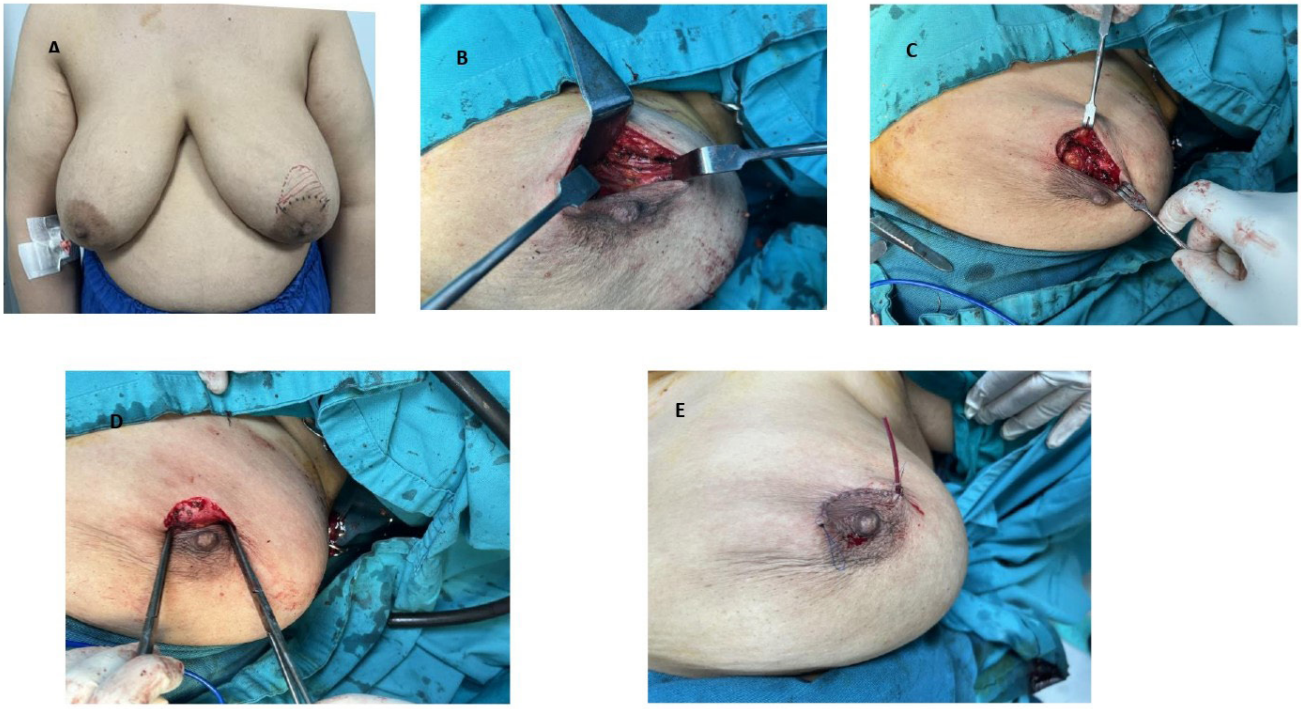

Figure 3: A – Preoperative drawing, B – Cavity after central duct excision, C – Closure of the cavity, D – De-epithelialised supra-areolar crescent according to the Al-Masad technique, E – After closure and small wound drain attached

distribution was presented as mean (± standard deviations). T-test was used for the differences between quantitative independent groups, while chi-square test and Fisher's exact test were used for the significance of association between categorical variables. The results were considered significant if the *p*-value was less than 0.05.

Results

From November 2019 to July 2022, 133 consecutive patients were enrolled in this study. Three cases were excluded (two cases in group A and one case in group B) due to a postoperative diagnosis of malignancy. Age was comparable in both groups.

Bilateral diseases were found in 15 patients of group A, with a total number of 80 procedures and in 11 patients of group B with a total number of 76 procedures (Table I).

The most common indication for surgery was significant copious nipple discharge (61.5% and 52.3%, respectively) (Table I).

The incision was half of the circum-areolar circumference in 82.5% and 88.2% of the total number of procedures performed in groups A and B, respectively. The pathological diagnoses were comparable in both groups, with MDE being the most common pathological diagnosis in both groups, followed by papillomatosis with/without atypia (Table II).

Postoperatively, the overall tactile nipple sensation at 12 months was better in group A than in group B, with no statistically significant difference. In detail, the nipple sensation was preserved in 71.2% versus 57.9%, it was impaired in 18.8% versus 27.6% and completely lost in 10% versus 14.5% in groups A and B, respectively with no statistically significant differences (Table III). Nipple retraction had a lower frequency after the Al-Masad modified technique (Figure 4) (2.5% versus 15.8%) with a statistically significant difference ***(p = 0.004)***. The postoperative haematoma rate was higher in group A, with no statistically significant difference. All other complications, namely NAC necrosis, infection and wound dehiscence, had comparable frequencies in both groups. Recurrence of symptoms was only observed in two cases of group A (Table III).

Table I: Preoperative parameters of both groups

	Group A (*n* = 65)	Group B (*n* = 65)	*p*
Age (years) Mean ± SD	51.85 ± 5.07	52.54 ± 5.52	0.564¶
Smoking *n* (%)	2 (3.1%)	0 (0%)	0.496*
Diabetes *n* (%)	6 (9.2%)	4 (6.2%)	0.510**
Bilaterality *n* (%)			
Unilateral	50 (76.9%)	54 (83.1%)	0.380**
Bilateral	15 (23.1%)	11 (16.9%)	
Indication for surgery *n* (%)			
Significant copious discharge	40/65 (61.5%)	34 /65(52.3%)	0.564**
Recurrent periductal mastitis	19/65 (29.2%)	24/65 (36.9%)	
Bleeding per nipple with no evidence of underlying malignancy	6/65 (9.2%)	7/65 (10.8%)	

¶ t-test, * Fisher's exact test, ** chi-square test, level of significance < 0.05

Table II: Intraoperative and pathological findings of both groups in relation to total number of procedures performed in each group

	Group A (*n* = 80) *n* (%)	Group B (*n* = 76) *n* (%)	*p***
Circumference of the incision			
⅓	14 (17.5%)	9 (11.8%)	0.319
½	66 (82.5%)	67 (88.2%)	
Weight of the specimen			
Mean ± SD	46.96 ± 6.50	47.01 ± 6.15	0.960
Median (Min – Max)	48 (32–65)	48 (35–62)	
Pathologic findings			
Duct ectasia with/without periductal mastitis	41 (51.3%)	42 (44.7%)	0.881
Duct papilloma	17 (21.3%)	15 (19.7%)	
Papillomatosis with/without atypia	22 (27.5 %)	19 (25.0%)	

** Chi-square test, level of significance < 0.05

Table III: Postoperative course in both groups

	Group A (*n* = 80) *n* (%)	Group B (*n* = 76) *n* (%)	*p*
Nipple sensation			
Normal	57 (71.3%)	44 (57.9%)	0.218**
Impaired	15 (18.8%)	21 (27.6%)	
Loss	8 (10%)	11 (14.5%)	
Complications			
Nipple retraction	2 (2.5%)	12 (15.8%)	***0.004*****
Haematoma	5 (6.3%)	2 (2.6%)	0.443*
NAC necrosis	1 (1.3%)	4 (5.3%)	0.201*
Infection	2 (2.5%)	1 (1.3%)	1.000*
Wound dehiscence	4 (5%)	2 (2.6%)	0.682*
Recurrence of symptoms	2 (2.5%)	0 (0%)	0.494*

* Fisher's exact test, **chi-square test, level of significance < 0.05

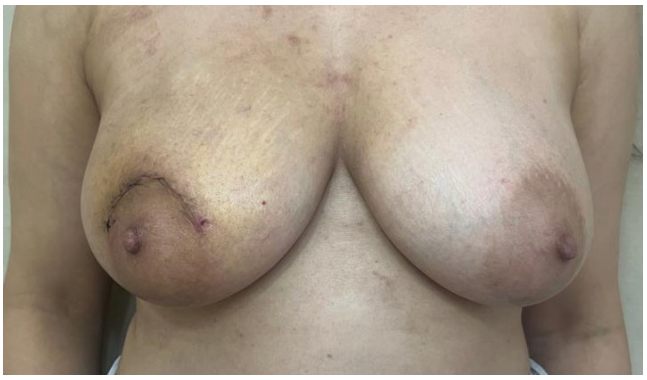

Figure 4: Early postoperative photo of right sided duct excision performed by the Al-Masad technique

Discussion

This study compared two different surgical approaches for central duct excision. Both techniques showed comparable results. However, the Al-Masad technique showed statistically significantly less nipple retraction. This group also showed better NAC sensation as well as less NAC necrosis, though these results were not statistically significant. Haematoma with subsequent infection was higher in group A. This was managed conservatively with no need for re-operations.

The Hadfield technique remains the standard procedure for managing severe cases of MDE. Postoperatively, loss of nipple sensation, nipple retraction and NAC necrosis are potential complications. The high incidence of postoperative complications resulted in several trials of modifications; however, none of them have been extensively studied compared to the Hadfield technique.

Dalci et al. retrospectively compared the round block incision, combined peri-areolar and radial incision versus the classical technique in 20 female patients. The authors reported a higher, but not significant, incidence of complications after the classical technique.[8] Postoperative nipple sensation is an important outcome after any breast surgical procedures.[9] Indeed, the nipple and areolar sensory nerve supply has been debated since its first description in the 1840s.[10]

Farina et al. reported that the most important nerve supply for the nipple and areolar is the anterior and lateral branches of the fourth intercostal nerve.[11] Later, Sarhadi et al. reported that the NAC is supplied by superficial and deep branches of the lateral cutaneous branch of the fourth intercostal nerve with less contribution of the second and fifth intercostal nerves from medial and lateral branches.[9,10] These nerves run from the inferolateral aspect to supply the NAC.[6]

Al-Masad planned his supra-areolar incision based on these anatomical studies, considering the inferolateral course of the sensory nerve supply.[6] This is supported by multiple studies reporting retained nipple sensation after the use of supra-areolar incisions in many breast procedures.[12,13] Regardless of the nerve course, the idea of de-epithelisation of skin with the creation of a newly vascularised bed for the advancement of NAC can contribute to better sensation

after the Al-Masad technique as it provides a good media for nerve regeneration.[6]

In our study, nipple sensation using the Al-Masad technique was preserved in 71.2%, impaired in 18.8% and lost in only 10%, while using the classical Hadfield technique, it was preserved in only 57.9%, impaired in 27.6% and completely lost in 14.5%. Despite not being statistically significant, there was a clear trend towards better nipple sensation using the Al-Masad technique. Similarly, Hagag et al. reported normal sensation in 75.9%, impaired sensation in 13.8% and loss of sensation in 10.3%.[14] In the initial report of Al-Masad, the nipple sensation improved over time – 22% after one month, 65% after six months and 89% after one year. Loss of sensation improved from 15% after six months, to only 4% after one year.[6]

In our study, postoperative nipple retraction was significantly less after the Al-Masad technique than the Hadfield technique, 2.5% and 15.8%, respectively. This is consistent with data from the literature. The incidence of nipple retraction in the original Hadfield technique was 10–18.2%.[6,8] In the study of Hagag et al. who adopted the Al-Masad technique, nipple retraction was 3.45%.[14]

Nipple retraction has been proposed as a potential cause of symptom recurrence.[6] In our study, symptom recurrence was not reported after the Hadfield technique; however, it was reported in two cases (2.5%) after the Al-Masad technique. Both patients had nipple retractions. The original Al-Masad technique was associated with recurrent symptoms in 2.5%,[6] while Dalci et al. reported 18.2% symptom recurrence after the Hadfield technique.[8] Necrosis of the NAC is a dreaded complication after breast surgery. In our study, NAC necrosis occurred in 1.3% and 5.3% after the Al-Masad technique and Hadfield technique, respectively. In the literature, NAC necrosis was reported in 2– 3.45% after the Al-Masad technique.[6,14] The incidence of NAC necrosis after the Hadfield technique has not been described.

It is worth mentioning that our study, to the best of our knowledge, represents the first randomised controlled study comparing the Al-Masad modified technique to the classic Hadfield technique. Another point of strength is that our study is the largest reported study for both techniques. Our results support the Al-Masad technique as a superior technique for MDE.

Limitations of our study include being a single-centre study with a short follow-up duration. Larger multicentre studies are required to confirm our results.

Conclusion

The Al-Masad technique is an effective technique for the surgical management of MDE. Compared to the Hadfield technique, this technique is associated with a statistically significant less incidence of nipple retraction, and improved nipple sensation, although this did not reach statistical significance. The authors recommend adopting the Al-Masad technique on a wider scale to further validate these results.

Conflict of interest

The authors declare no conflict of interest.

Funding source

No funding was required.

Ethical approval

After obtaining the ethical approval from the local Institutional Review Board (0304837) and registering in the clinical trials registry (NCT04744766), a prospective randomised trial was carried out including all patients who underwent mammary duct excision in a tertiary university institute (Alexandria Main University Hospital).

ORCID

MA Alhussini https://orcid.org/0000-0002-3169-4338
MS Foula https://orcid.org/0000-0003-1951-635X
H Fayed https://orcid.org/0000-0001-9971-2320
AM Eldamati https://orcid.org/0000-0003-4385-3161

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