

# Prophylactic Use of Negative Pressure Wound Therapy in High-risk Patients Undergoing Oncoplastic and Reconstructive Breast Surgery

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**Background:** Negative pressure wound therapy (NPWT) has emerged as an adjunct to reduce wound complication rates in many surgical domains. This study investigated the prophylactic use of PICO NPWT in high-risk patients undergoing oncoplastic and reconstructive breast surgery.

**Methods:** This was a prospective multicenter national audit. The findings were compared against Association of Breast Surgery/British Association of Plastic, Reconstructive and Aesthetic Surgeons (ABS/BAPRAS) Oncoplastic Guidelines for best practice.

**Results:** Data from 267 patients were included from seven centers. All patients had at least one high-risk factor for postoperative wound complications, whereas 78 patients (29.2%) had more than one. Thirty-six patients (13.5%) developed postoperative wound complications. An estimated 16 (6%) developed skin flap necrosis, wound dehiscence occurred in 13 patients (4.9%), and 15 patients (5.6%) developed postoperative wound infection. Eleven patients (4.1%) required further surgery due to wound complications. In total, 158 patients underwent mastectomy with immediate implant reconstruction. Postoperative wound complication rate was comparable in this subgroup (n = 22; 13.9%). Implant loss rate was 3.8%, which was within the 5% target mentioned in the ABS/BAPRAS guidelines. The estimated total cost saving was US \$105,600 (£84,613) and US \$395.50 (£316.90) per patient. Wound infection rate (5.6%) was much lower than the 25% reported by both iBRA study and National Mastectomy and Breast Reconstruction Audit.

**Conclusions:** Our study suggests that prophylactic use of NPWT in oncoplastic and reconstructive breast surgery results in low rates of wound-related complications with associated healthcare cost benefits in patients with high-risk factors for wound-related complications. However, a prospective randomized control trial is required.

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## INTRODUCTION

Breast cancer is the most common cancer in women across the world. Every year, around 55,000 women are diagnosed with breast cancer in the United Kingdom.<sup>1</sup> The therapeutic options and management strategies for breast cancer are complex and ever-evolving, especially with advances in oncoplastic and reconstructive breast surgery. Surgery remains the mainstay treatment for breast cancer patients. However, wound-related complications after breast surgery are relatively common, with reported rates varying between 7% and 31% in the literature.<sup>2,3</sup> The rate and range of wound-related complications are higher for patients with medical co-morbidities (eg, diabetes) or due to the type of procedure performed (eg, implant-based immediate breast reconstruction). These complications are important due to not only their morbidity and psychological impact (eg, loss of implant breast reconstruction

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due to infection), but also delays that can occur to the receipt of adjuvant treatment. These complications also have a significant economic aspect. The mean NHS cost of wound care over 12 months has been estimated to be US \$9110 (£7300) per wound, ranging from US \$7488 (£6000) to US \$17,098 (£13,700) per healed and unhealed wound, respectively.<sup>4</sup> Irwin et al demonstrated that the mean cost per reconstruction failure is US \$18,597 (£14,902).<sup>5</sup>

There is growing evidence that negative pressure wound therapy (NPWT) on closed wounds can reduce the risk of postoperative wound complications.<sup>2-4</sup> NPWT isolates the wound and manages exudate, thereby preventing infection and cross-contamination.<sup>2</sup> It furthermore reduces edema, stimulates angiogenesis, promotes contraction of the wound edges, reduces wound margin tension, improves lymphatic outflow, and maintains a moist wound healing environment.<sup>3,6</sup> All these factors contribute to a lower wound infection rate and to fewer problems in wound healing. Evidence suggests NPWT can accelerate healing times and improve patients' quality of life.<sup>6,7</sup> Prophylactic use of NPWT has shown reduction in wound complication rates in high-risk patients undergoing abdominal and colorectal surgery, and cesarean section.<sup>8</sup> However, there is limited evidence regarding its use prophylactically in patients at higher risk for developing wound-related complications undergoing oncological and reconstructive breast surgery.

Fogacci et al have studied the effect of negative pressure therapy with PICO as a preventive measure to reduce surgical-site infection (SSI) in 100 high-risk patients undergoing breast surgery. They demonstrated that PICO, used prophylactically in high-risk patients, helps control and reduce the incidence of wound infection and ischemia.<sup>9</sup> However, further evidence is lacking, which demonstrates the efficacy of NPWT in breast surgery, which patient groups may benefit from such additional therapy, and what the relative complication rates are when compared with the national standards as defined by UK guidelines.

We therefore aimed to conduct a multicenter audit to evaluate the effectiveness of a NPWT system, PICO, used prophylactically in patients with high-risk factors for wound-related complications undergoing oncological and reconstructive breast surgery between October 2018 to November 2019.

## METHODS

### Study Design and Setting

A prospective multicenter audit was conducted at seven breast centers in the United Kingdom between October 2018 to November 2019. Ethical approval was not required, as the study was classified as an audit according to the NHS Health Research Authority online decision tool (<http://www.hra-decisiontools.org.uk/research/>). All centers obtained local audit approval.

### Inclusion Criteria

Women over the age of 18 years who were considered high-risk for wound-related complications and undergoing one of the following breast surgical procedures were included in the study:

### Takeaways

**Question:** Does prophylactic use of NPWT lower wound complications in high-risk patients undergoing breast oncological and reconstructive surgery?

**Findings:** Our study suggests that prophylactic use of NPWT in oncological and reconstructive breast surgery results in low rate of wound-related complications with associated healthcare cost benefits in patients with high-risk factors for wound-related complications.

**Meaning:** NPWT can be a useful adjunct to prevent wound-related complications in patients with high-risk factors for developing wound complications undergoing breast oncology and reconstruction.

- Mastectomy with immediate implant-based breast reconstruction (both prepectoral and subpectoral)
- Oncological procedure following wide local excision or quadrantectomy
- Reduction mammoplasty/mastopexy (done for symmetry at the same time as the therapeutic procedure)
- Delayed breast reconstruction

Women were defined as being high-risk for developing wound-related complications, if they had one or more of the following (based on clinical decision and as mentioned in the Association of Breast Surgery (ABS) and the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS) guidelines)<sup>10</sup>:

- Overweight [body mass index (BMI) 25–29.9 kg/m<sup>2</sup>] based on clinical consensus, 11] or obese (BMI >30 kg/m<sup>2</sup>)
- Current smoker
- Type I or II diabetes (insulin or noninsulin-dependent)
- Previous radiotherapy to the affected breast
- Neoadjuvant chemotherapy
- Currently on corticosteroids (for any indication)

### Exclusion Criteria

Patients under the age of 18, those who did not undergo any breast oncological or reconstructive procedure (ie, patients undergoing simple mastectomy or wide local excision), those who had known allergies to the dressings to be used, or had a history of poor compliance to medication or medical devices were excluded.

### Outcomes

Data on the following surgical outcomes were collected as defined by the iBRA (implant breast reconstruction evaluation) study<sup>11</sup>:

- Skin flap necrosis: Any area of skin loss on the flaps
  - Minor: managed conservatively with dressings
  - Major: requiring intervention: debridement.
    1. Requiring debridement in clinic
    2. Requiring surgical debridement (under general anesthesia)
- Wound dehiscence: Separation of the skin edges at the wound site
  - Minor: managed conservatively
  - Major: requiring return to theater for intervention

- Infection: A red, hot, swollen breast associated with one of the following: raised temperature above normal level, positive wound culture, pus at the wound site, a raised white cell count
  - Minor: requiring oral antibiotics
  - Major: requiring admission for intravenous antibiotics or surgical intervention
- Implant loss
- Delay in adjuvant therapy

We compared our study findings against the outcomes from the National Mastectomy and Breast Reconstruction Audit (NMBRA)<sup>12</sup> and iBRA study,<sup>11</sup> as mentioned in the ABS/BAPRAS Oncoplastic Guideline for best practice,<sup>10</sup> which included patients who received “standard dressings” and not NPWT.

#### Sample Size Calculation

Best practice guidelines in United Kingdom aim to audit techniques that reduce local complications after breast oncoplastic and reconstructive procedures. NMBRA<sup>12</sup> reported that 7.6% patients returned to theatre for local complications (wound infection or skin flap necrosis requiring debridement, and hematoma) after breast surgery, hence allowing for a wound complication rate requiring return to theatre of 10% in a nonstudy population across all procedures covered. It was calculated statistically that to see a 50% decrease in complication rates, 238 patients needed to be recruited. Allowing for a 10% dropout rate, the study aimed to recruit 260 patients between October 2018 and November 2019.

#### NPWT Device

In NPWT, a closed, sealed system is used to achieve negative pressure. A sterile dressing covers the wound and is sealed with an occlusive drape. A nonsterile vacuum pump connected to a suction tube from the wound dressing provides continuous suction. Negative pressure of 80 mm Hg is maintained at the wound surface by PICO (Smith & Nephew Medical Limited, Hull, United Kingdom), a portable canister-less, single-use (disposable after 7 days) NPWT system. The protocol involved using PICO dressing prophylactically in high-risk patients in place of the standard dressings<sup>13</sup> (Fig. 1).



**Fig. 1.** A photograph of the PICO single-use NPWT system in position on a patient who had bilateral breast oncoplastic surgery.

## SURGICAL TECHNIQUE

The type of surgery was decided based on tumor site, patient choice, and oncological characteristics. The surgery was carried out in a standard manner by breast oncoplastic and reconstructive surgeons. The implants were placed either in the prepectoral or subpectoral space with or without acellular dermal matrix and dermal sling. Contralateral reduction mammoplasty or mastopexy or risk-reducing mastectomy with or without reconstruction were performed simultaneously. The wound was closed with subdermal sutures using 3/0 undyed Vicryl or Monocryl and skin closure using running subcuticular sutures (either 3/0 Vicryl or 3/0 Monocryl). Implant-based breast reconstruction was performed as a single or two-stage procedure depending on surgeon's practice and patient choice.

The wound dressing was applied after skin closure immediately in theater, following which the vacuum pump was connected. The dressings were checked before the patient was discharged from the hospital to make sure the negative pressure system was working. Patients were taught about the device and were discharged home with it in place.

Patients were seen 7 days postoperatively either by a member of the surgical team or a breast care nurse for wound check, removal of the PICO dressing or to decide if it was to be used for another week (based on clinical assessment). Patients with implant-based reconstruction had two drains, one deep and another superficial to biological mesh or dermal sling. These drains stayed till the drain output was less than 20 mL over 24 hours. The drains were removed between 5 days and 2 weeks.

## DATA COLLECTION

Data were prospectively collected in a pre-designed audit proforma.

## STATISTICAL METHODS

All data analyses and management were performed using RStudio, version 1.4.1106 (R Foundation for Statistical Computing, Vienna, Austria). Results have been presented as percentages, mean  $\pm$  SD, and range. Findings were compared against the outcomes from two national audits, NMBRA<sup>12</sup> and iBRA,<sup>11</sup> as mentioned in the ABS/BAPRAS Oncoplastic Guideline for best practice.<sup>10</sup> Due to the difference in the study population (high-risk patients only in the study versus all patients in the national audits), statistical tests for significance were considered inappropriate.

## RESULTS

A total of 271 high-risk patients were recruited in the study. Four had incomplete data and hence, were excluded from the final analysis. Finally, 267 patients were included in the study from seven breast centers across the United Kingdom. All patients had at least one high-risk factor for postoperative wound complications, and 78 patients (29.2%) had more than one high-risk factor. The risk factor profile of the patients is shown in Table 1.

**Table 1. Demographic and Clinical Characteristics of Patients Undergoing Breast Surgery**

Characteristic	N (%)
BMI group, kg/m <sup>2</sup>	
25–29.9	141 (52.8)
30–34.9	59 (22.1)
>35	38 (14.2)
Current smoker	40 (14.9)
Previous radiotherapy	17 (6.4)
Neoadjuvant chemotherapy	30 (11.2)
Diabetes	15 (5.6)
Steroid use	5 (1.9)

**Table 2. Breast Procedures Performed**

Surgery	N (%)
Mastectomy with implant reconstruction	158 (59.2)
Oncoplastic procedure after wide local excision or quadrantectomy	52 (19.5)
Reduction mammoplasty/mastopexy (done for symmetry at the same time as the therapeutic procedure)	45 (16.8)
Delayed reconstruction	12 (4.5)

The patients underwent different breast oncoplastic procedures (Table 2), but mastectomy with immediate implant-based reconstruction (both prepectoral and subpectoral) (59.2%) was the most commonly performed procedure.

Forty patients (14.9%) developed postoperative complications, and 36 patients (13.5%) developed postoperative wound complications. Four patients had postoperative bleeding/hematoma formation.

Sixteen patients (6.0%) developed skin necrosis, which was managed conservatively in 15 of 16 patients (5.6%). Wound dehiscence was seen in 13 patients (4.9%) with three of 13 patients (1.1%) requiring operative intervention. Fifteen patients (5.6%) developed postoperative wound infection, with six of 15 patients (2.3%) requiring re-admission or further surgery. In the whole cohort, 11 patients (4.1%) required further surgery, and eight patients (3.0%) had a delay in receiving adjuvant therapy due to wound-related complications (Table 3).

The mean duration of PICO use was 6.6±1.9 days [range 1–13 days]. An estimated 48.6% patients had PICO for 7 days. No adverse or allergic reaction to the PICO dressing was noted in the study.

A subgroup analysis was performed for the 158 patients who underwent mastectomy with immediate implant-based reconstruction (Table 4). Of these, 83.1% had the implant placed in the prepectoral position, whereas 16.9% had a subpectoral implant. Acellular dermal matrix was used in 93.1% of patients, and a dermal sling was used in 31.7%. The mean weight of the mastectomy specimen was 728±629.64g. The average size of the implant used was 473±145.59g.

In this subgroup, 22 of 158 patients (13.9%) developed postoperative wound complications. Skin necrosis was seen in 10 patients (6.3%), but only one of the 10 patients (0.6%) required further surgery. Major wound dehiscence requiring operative intervention was seen in three patients (1.9%), and eight patients (5.1%) developed

**Table 3. Wound Complication Rates in the Whole Cohort (N = 267)**

Wound Complication	n	% (n/N)
Skin necrosis	16	5.9
• Minor	15	5.6
• Major	1	0.4
Wound dehiscence	13	4.9
• Minor	10*	3.8
• Major	3 (*9 of the minor were T-junction dehiscence)	1.1
Wound infection	15	5.6
• Requiring admission/surgery	6	2.3
Infection with skin necrosis	3	1.1
Infection with wound dehiscence	6	2.3
Further surgery	11	4.1
Implant removal (N = 158)	6	3.8
Delay in receipt of adjuvant therapy	8	3.0

**Table 4. Wound Complication Rates in a Subgroup of Patients Undergoing Mastectomy with Immediate Implant Reconstruction (N = 158)**

Wound Complication	n	% (n/N)
Skin necrosis	10	6.3
• Minor	9	5.7
• Major	1	0.6
Wound dehiscence	7	4.4
• Minor	4	2.5
• Major	3	1.9
Wound infection	8	5.1
• Requiring admission/surgery	5	3.2
Infection with skin necrosis	1	0.6
Infection with wound dehiscence	4	2.5
Further surgery	7	4.4
Implant removal	6	3.8
Delay in receipt of adjuvant therapy	4	2.5

wound infection. Implant removal was required due to complication in six patients (3.8%; Table 4).

A comparison of our findings with the outcomes from the iBRA, NMBRA, and National Quality Criteria for Breast Reconstruction<sup>11,12</sup> is presented in Table 5.

The mean cost per reconstruction failure is estimated to be US \$17,586 (£ 14,902) by Irwin et al.<sup>5</sup> Based on the findings of the iBRA and NMBRA, 14 patients (9%) in the study were expected to have implant loss. The estimated cost due to reconstruction failure would have been US \$260,368 (£208,628). However, in the study, six patients had implant loss amounting to a cost of US \$111,586 (£89,412). The total cost of using the PICO system in the study was estimated to be US \$43,184 (£34,603). Hence, we estimated a total cost saving of US \$105, 597 (£ 84,613), and US \$395.50 (£ 316.90) per patient (Table 6).

## DISCUSSION

Our multicenter prospective study aimed to evaluate the occurrence of wound-related complications in

**Table 5. Comparative Analysis with Outcomes from iBRA, NMBRA, and National Quality Criteria for Breast Reconstruction**

Wound Complication Rates (in %)	Our Study	iBRA	NMBRA	National Quality Criteria for Breast Reconstruction
Skin necrosis	5.9			
• Minor	5.6			
• Major	0.4			
Wound dehiscence	4.9			
• Minor	3.8			
• Major	1.1			
Wound infection	5.6	25 (23–27)	25	<10
• Requiring admission/surgery	2.3			
Infection with skin necrosis	1.1			
Infection with wound dehiscence	2.3			
Further surgery due to complications	4.1	18 (16–20)	5	<5
Implant removal	3.8	9 (8–10)	9	<5
Delay in receipt of adjuvant therapy	3.0			

**Table 6. Cost Analysis Rate of Implant Loss as per iBRA Study and NMBRA = 9%**

iBRA and NMBRA		Our Study	
Estimated number of patients with implant loss	14	No. patients with implant loss	6
Estimated cost due to reconstruction failure	US \$260,367 (£2,08,628)	Estimated cost due to reconstruction failure	US \$111,586 (£89,412)
		Cost of NPWT per patient	US \$161.74 (£129.60)
		Total cost of NPWT use in the study	US \$43,184 (£34,603)
		<b>Total</b>	<b>US \$154,770 (£1,24,015)</b>
<b>Total cost savings</b>	<b>US \$105,597 (£84,613)</b>		
<b>Cost saving/patient</b>	<b>US \$395.49 (£316.90)</b>		

Number of patients who underwent mastectomy with implant-based reconstruction = 158. Mean cost per reconstruction failure (5) = US \$18,597 (£14,902).

high-risk patients undergoing therapeutic breast surgery using prophylactic NPWT, the PICO system. To our knowledge, this is the only multicenter study evaluating the role of prophylactic NPWT in high-risk patients undergoing different breast oncologic and reconstructive procedures.

In addition to the commonly recognized<sup>10</sup> high-risk factors for wound complications such as obesity (BMI >30 kg/m<sup>2</sup>), diabetes (type 1 and type 2), smoking, prior radiotherapy to the affected breast, neoadjuvant chemotherapy, and steroid use; we also included patients who were overweight (BMI 25–29.9 kg/m<sup>2</sup>) in the study as being high-risk for wound complications. Ilonzo et al studied data for 67,450 patients undergoing breast reconstruction for breast cancer, using the National Surgical Quality Improvement Program database between 2005 and 2014 and found that being overweight (odds ratio 1.38, CI 1.23–1.55) was one of the independent risk factors that were associated with increased wound complications in patients undergoing all or any forms of reconstruction after mastectomy.<sup>14</sup> Further, the decision to include patients in this BMI category as high-risk and candidates for prophylactic use of NPWT was based on clinical consensus by oncologic and reconstructive breast surgeons at the participating centers, based on the findings of the iBRA audit identifying increasing BMI as an important risk factor for wound complications, especially in patients undergoing implant-based surgery.<sup>11</sup>

We compared our outcomes with the findings from the iBRA study and NMBRA, as mentioned in the ABS/

BAPRAS Oncoplastic Guideline for best practice.<sup>10–12</sup> We found that our wound infection rate (5.6%) was lower than the 25% reported by both iBRA and NMBRA. It is also lower than the established norm by the National Quality Criteria for Breast Reconstruction at 10%. Our further surgery (4.1%) rate due to complications is also within the criteria established by the National Quality Criteria for Breast Reconstruction at less than 5%. A key performance indicator for implant-based breast reconstruction is implant loss rate. Both the iBRA study and NMBRA have reported an implant loss rate of 9%, whereas the UK breast reconstruction best practice guidelines by ABS/BAPRAS include an implant loss rate target of less than 5%. The implant loss rate in our study cohort was favorable at 3.8%.<sup>10–12</sup>

The uses of NPWT on closed incisions in different surgical specialties has been widely reviewed. Hyldig et al in their systematic review and meta-analysis of randomized clinical trials of the use of NPWT for closed surgical incisions found that NPWT reduced the rate of wound infection and seroma with no significant effect on wound dehiscence.<sup>15</sup> A meta-analysis by Semsarzadeh et al on the use of NPWT on closed incisions found a 29.4% reduction in SSI; wound dehiscence rates approximately halved when NPWT was used. However, due to the heterogeneity between the included studies, they could not conclude any general recommendation.<sup>16</sup>

Another study that aimed to evaluate the prophylactic use of NPWT after cesarean section by Yu L et al found similar heterogeneity but their results suggested a reduction in SSI and overall wound complications.<sup>17</sup> Strugala et al found a significant reduction in SSI,

wound dehiscence, and length of hospital stay in their meta-analysis.<sup>8</sup> In a recent meta-analysis, Saunders et al reviewed 29 studies enrolling 5614 patients with risk factors for surgical-site complications and found that the number of SSI, the odds of wound dehiscence, seroma, necrosis, and mean length of hospital stay were all significantly reduced.<sup>18</sup>

The studies for the use of NPWT on closed incisions in breast surgery are evolving. In a recently published systematic review and meta-analysis, Chicco et al evaluated the current evidence on the prophylactic use of NPWT in prosthetic breast reconstruction and found that it reduces the rate of overall wound complications and mastectomy flap necrosis.<sup>19</sup> In another systematic review and meta-analysis, Cagney et al also reported that compared with conventional non-NPWT dressings, prophylactic application of NPWT in complicated breast wounds and wounds after breast reconstruction (with or without the use of implants), and after reduction mammoplasty is associated with significantly fewer surgical-site complications, including SSI, seroma, wound dehiscence, and wound necrosis.<sup>20</sup>

Galiano et al studied the effect of NPWT dressing (PICO) versus standard wound-care dressing in a multicenter randomized control trial on 200 patients who had bilateral reduction mammoplasty randomized to right or left breast for up to 14 days to enable within-patient comparison. They found significantly fewer wound healing complications and a significantly lower incidence of dehiscence in the NPWT sites.<sup>21</sup>

In a similar prospective randomized study, Tanaydin et al reported their use of NPWT on patients who underwent bilateral reduction mammoplasty. In their review of 32 patients who underwent bilateral reduction mammoplasty, NPWT was applied to one breast and fixation strips to the other breast, with significant lower wound complications and a significant improvement in quality of scarring in favor of the NPWT-treated sites.<sup>22</sup>

Holt et al published a case series of 24 consecutive patients. Of these patients, 21 underwent therapeutic mammoplasty, whereas three had Wise pattern skin-sparing mastectomies and immediate implant or inferior dermal flap technique. They reported a lower incidence of wound breakdown (4.2%) on the side treated with PICO (therapeutic side) in comparison with 16.7% rate of wound breakdown of the side treated with conventional dressing (reduction side).<sup>23</sup>

Kim et al have reported their use of incisional NPWT in patients who underwent mastectomy and expander-based reconstruction. In their retrospective review, 228 breasts (206 patients) were included. They found that the incisional NPWT group had a lower overall mastectomy flap necrosis rate (8.9% versus 23.5%;  $p = 0.030$ ) and major mastectomy flap necrosis (2.2% versus 13.7%;  $p = 0.031$ ) compared with the conventional dressing group.<sup>24</sup>

Our study demonstrates that there is a potential role for prophylactic use of NPWT in patients with high-risk factors for wound-related complications undergoing breast oncologic and reconstructive surgery. However, our study has a few limitations. It does not have an internal

control group with similar clinical characteristics who did not receive NPWT. The sample size was calculated based on a composite outcome (ie, return to theatre) as per the NMBRA<sup>12</sup> study, rather than a single critical outcome. There is a need to conduct sufficiently powered randomized trials in breast cancer patients who are at higher risk of developing wound complications and evaluating the role of prophylactic use of NPWT. Further, in this study, patients undergoing implant-based reconstructive procedures were analyzed as a subgroup. However, considering the complexity and complication rate of implant-based reconstruction, there is a need to study the effectiveness of prophylactic NPWT in these patients explicitly.

## CONCLUSIONS

Our study suggests that prophylactic use of NPWT in patients with high-risk factors for wound complications result in low rates of wound-related complications with associated healthcare cost benefits. A prospective randomized controlled trial is required to further evaluate the prophylactic use of NPWT and define which patient subgroups are most likely to benefit from NPWT.

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## DISCLOSURES

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