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Technical Note



Healthcare delivery to elderly and unfit patients with breast disease and comorbidities under an outpatient regime: A report of a personal surgical technique named "Cut&Sew"

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ABSTRACT

Introduction: A growing need for proper geriatric assessment and short-stay surgical programs supported by the availability of less invasive approaches, even in ambulatory settings, is being recognized as a feasible option for breast cancer patients with comorbidities who are usually distressed after standard surgery with ordinary hospitalization. Few studies have been conducted in Italian breast centers with dedicated techniques and approach for frail patients with breast diseases due to a jeopardized approach to ambulatory surgery among institutions. Methods: This study included 58 women diagnosed with breast disease and comorbidities between March 2019 and December 2022 at the Ambulatory of Senology of San Giacomo Hospital in Novi Ligure (AL, Italy) and Civil Hospital in Ovada (AL, Italy). The patients were evaluated by a multidisciplinary consensus according to the guidelines provided to limit sentinel lymph node biopsy (SLNB) in older women. This kind of ambulatory surgery technique has been designed for i) patients with advanced age and/or comorbidities, ii) frail patients who psychologically do not accept other kinds of surgery, iii) patients who do not require SLNB, and iv) patients who need a surgical biopsy for lesions classified as B3 or small lesions with dubious radiological imaging. With this technique, the quadrant and whole breast may be removed in an outpatient setting with local anesthesia to limit blood loss by immediately cutting and suturing small portions of the gland. Local anesthetic infiltration is sequential and occurs stepwise before providing short passages of approximately 2 cm during resection and immediately suturing the surgical wound. This overclock technique, named "Cut&Sew," requires no more than 20-25 min and allows for a 1-2 h patient discharge with no drainage. The follow-up period was set at 60 months during routine yearly visits.

Results: The patients were older or super-older with most primary pT1/pT2 tumors and ductal type cancers, which were distributed in molecular subtypes Luminal A (37.1 %) and Luminal B (41.5 % Luminal B, with 11.2 % being HER2 positive). The tumour grade was mostly G2-G3. Mastectomy was performed in 10 patients, whereas quadrantectomy was performed in 48 patients, with the majority of tumors localized in Q1.

While accompanied by a relative or a caregiver, all 58 patients acceded the "Cut&Sew" surgical technique in an ambulatory setting reporting negligible pain during the surgery and no pain within 10 days post-surgery. No post-operative complications or readmissions were recorded, and no discomfort or recurrence was detected during scheduled visits. Finally, the extent of satisfaction with the overall surgery was recorded immediately and corroborated by most patients during the follow-up period.

Conclusions: Although the small volume of cases collected does not allow for a controlled study necessary to evaluate the safety and efficacy of this technique for approaching frail and older women with comorbidities, through the "Cut&Sew" surgical technique, frail, older, and super older patients may benefit from a minimal psychological impact of surgery, while improving the patients disease-free life so to corroborate the advised surgical de-escalation but avoiding undertreatment for this kind of patient category. Moreover, a stricter assessment of patient pain and overall satisfaction with the collection of a larger amount of reliable data could allow this technique to be extended to frail and/or older patients as a valuable and safe alternative to the more common hospitalization with general anesthesia. Other advantages include reduced hospitalization costs for sanitary structures.

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Introduction

Despite the prevalence, healthcare expenditures and hospitalization experiences have long been recognized as important considerations among older populations with multiple chronic conditions. However, there remains poor consensus in the oncology community regarding the optimal mode of management for older patients with breast cancer (BC). This might be because of their comorbid conditions, short life expectancy, and high cancer stage [1–3]. Indeed, the recent extension of age in many countries for breast screening from 65 to 69 years has led to a change in the definition of older patients to those over 70 years, who are not included in a screening program [4–6]. Therefore, BC diagnosis in this group is usually delayed through a symptomatic breast clinic or as an incidental finding while investigating another illness [7].

Such a well-documented relationship between older age and a delay in BC diagnosis is associated with larger tumors and more advanced stage at presentation [7–9], a situation usually referred to as neo-adjuvant hormonal medical treatment for 4–6 months after which patients either continue with medical therapy or opt for surgery facing some risks [10]. The percentage of patients not receiving any surgery, axillary surgery, increases with age in many countries [11], and about one-third of treatment omissions were due to patient preference [12]. The omission of primary surgery in unselected older women with operable BC who were fit for the procedure resulted in an increased rate of progression and mortality [8,13].

The growing need for proper geriatric assessment [14–16] and short-stay surgical programs supported by the availability of less invasive approaches, even in ambulatory settings, are recognized as feasible options for patients with BC with comorbidities [10,17,18]. Outpatient treatment is longer a contraindication for most pathologies, as the outpatient surgical complication rate has become very low [19]. Surgical de-escalation procedures even in an-ambulatory setting are recognized as a feasible option in these patients to prevent or palliate breast or chest wall symptoms [10].

Ambulatory surgery allows for the patient's discharge within 12 h, same-day surgery within 24 h, and non-ambulatory surgery involves at least a one-night stay in the hospital. Ambulatory surgery or same-day surgery is increasingly offered to patients [18,20-26] owing to the shorter monitoring time in the hospital and a decreased waiting time for surgery. The major benefit to the patient compared to the inpatient regime involves psychological distress and satisfaction [23], especially when major breast surgery and reconstruction need to be performed [26]. Diminution of anxiety and depression with same-day surgery management has been outlined [27]. Additionally, ambulatory surgery did not significantly differ from non-ambulatory surgery in terms of surgical risks [26,28], even if frailty was demonstrated to be associated with a stepwise increase in the incidence of complications after elective ambulatory surgery [29]. Rothenberg et al. [30] outlined such complications as a partial mediator in the association between frailty and readmission. This reinforces the meaningful role played by the continuity of care by a dedicated physician after ambulatory surgery, with further reinforcement to the patients of the post-operative recommendations, along with personalized follow-up with routine visits [31].

The possibility of being able to offer an ambulatory surgery would allow for treating a large number of patients and decreasing waiting times while reducing sanitary costs. In this respect, significant differences among institutions exist when age, co-morbidities, unilateral/bilateral surgery, and BMI are monitored [20,22,25,27,29,31]. Such great institutional bias may contribute to increasing the use of discretionary surgical procedures in ambulatory surgery for breast diseases [32]. Therefore, the need for advisable and targeted surgical techniques requiring no drainage and local anesthesia [33] limiting pain, vomiting, perioperative anxiety, and post-operative complications in frail and comorbid patients is strongly advised [27].

After searching PubMed for "breast ambulatory surgery in Italy," only 15 papers emerged that evidence the structures that provide

specialist outpatient services [10,18,20,34–45]. Over time, similar to the trend of reduction in the number of hospitals, there has been a contraction in the number of these structures. Recently, a declining trend has been confirmed in both hospital beds and hospitalizations in the ordinary and daytime regimes. Simultaneously, many outpatient activity segments are growing, especially for complex specialist services; however, the value is not proportionally appreciated owing to the significant delay in updating outpatient rates at a national level [46,47]. Consequently, few studies have been conducted on Italian breast centers, where ambulatory surgery is not yet routinely performed with dedicated techniques and approaches for frail patients with breast diseases [18,20,34,35,38,39].

Senology is well adapted for ambulatory surgery, which will be well accepted if adequate information is provided beforehand by the family doctor and pursued by the surgical team [20,48]. In our opinion, outpatient surgery represents a precious and safe alternative only when performed in a context in which the patient is accurately prepared preoperatively and strictly controlled post-operatively. However, ambulatory management has become the standard in many countries for the surgical treatment of BC [17,21–33]. The monitoring duration in hospitals is shorter (less than 12 h) and allows for decreased cost and waiting time for surgical care. Nevertheless, the Italian context shows a jeopardized map with hospitals where none are provided as an outpatient structure capable of offering any kind of surgical regime.

Finally, difficulties are met when exploring the literature for surgical techniques targeted at older and frail patients with comorbidities and those that do not require drainage or specific anesthesiologic practices, even for major breast surgery. In this study, we describe a personal technique named "Cut&Sew," specifically designed for treating older, super-older, and frail comorbid patients with both breast lesions of unknown nature and malignant breast disease.

Methods

This study included 58 women diagnosed with breast disease and comorbidities between March 2019 and December 2022 at the Ambulatory of Senology of San Giacomo Hospital in Novi Ligure (AL, Italy) and the Civil Hospital in Ovada (AL, Italy). The patients were evaluated by a multidisciplinary consensus according to the guidelines provided to limit SLNB in older women [10,12,15,49–51] prior to surgery using the "Cut&Sew" technique. Indeed, this procedure has not been targeted to involve SLNB since the literature (The Society for Surgical Oncology, SSO, and the Choosing Wisely Foundation) [52,53] identified a list of common practices in surgical oncology that recommend against the routine use of SLNB in women over 70 with T1NOMO hormone receptor positivity.

This type of surgery is designed for vulnerable patients who may or may not have comorbidities and disabilities. Since frailty is a dynamic symptom of disease or injury increasing the vulnerability of the patient to stressors that often causes difficulties in hospitalization [1,2,7,9,14,15,30]. The eligibility criteria for the "Cut&Sew" approach are: i) patients with advanced age and/or comorbidities; ii) frail patients who psychologically do not accept other kind of surgery; iii) patients who do not require sentinel lymph node biopsy (SLNB); and iv) patients who need surgical biopsy for lesions classified as B3 or a small one with a dubious radiological image.

Since the "Cut&Sew" approach does not imply any routine use of sedation, a mild sedative could be administrated if needed or if requested by the patient. Furthermore, the patients were asked about the intensity of pain perceived during the intervention. Pain was also monitored from 0 to 10 days after surgery by direct contact with the patients or their relatives or caregivers.

Medication was administered 1 week after surgery, when information about wound-related status and benefits/issues from the intervention were collected. The satisfaction level from the intervention was evaluated before the patient was discharged and at a follow-up between

6 and 12 months by directly asking the patients at planned senological visits. Complications (seroma, hematoma, wound infection, and/or dehiscence) were evaluated during a median follow-up period of 60 months.

No controlled studies have compared the safety and efficacy of this technique in frail and older women with comorbidities. This needs to be further evaluated by collecting more cases and providing a comparison between routine techniques performed under general anesthesia and this kind of faster approach for the same patient category.

Written informed consent to publish the information presented in this case series was obtained from the patients or their guardians prior to submission. Ethics approval was not required as this case report was deemed not to constitute research, as provided by the Intercompany Ethics Committee of Health Hospital Agencies A.O. of Alessandria, ASL AL., and ASL VC. The study has been registered in ResearchRegistry.com and coded as "researchregistry7955." This case series was reported in accordance with the PROCESS guidelines [53].

Surgical technique

With the "Cut&Sew" technique both a quadrant (Fig. 1A, B, and C) and the whole breast (Fig. 2A, and B) may be removed in an outpatient setting using local anesthesia to limit blood loss by immediately cutting and suturing small portions of the gland (Fig. 1D, E, F, G, H and Fig. 2D, E, F). A local anesthetic was injected for a length of approximately 2–3 cm and breast resection was started up to the pectoral plane using both a scalpel and scissors. The infiltration of the local anesthetic is also sequential and occurs in small quantities in both the subcutaneous and prepectoral planes (Fig. 2C). Very short passages of approximately 2 cm (Fig. 3A) during resection aimed to better control any bleeding and to immediately suture the surgical wound with 3/0 resorbable stitches while the skin was sutured with simple stitches or an intradermic suture (Fig. 1I, Fig. 3BI, and 3BII).

Any painful sensations in the surrounding tissues that are not covered by local anesthesia are limited by avoiding the use of an electric scalpel, which is used only with bipolar forceps to stop blood loss. The learning curve was not explicitly assessed because this technique can be adopted by any advanced breast surgeon. However, ultrasonography is necessary for this surgical approach.

The mean operative time is between 20 and 25 min. In 1–2 h after surgery, when the patient feels well, she can go back home as no drainage is needed even for mastectomies, and no administration of sedative, anti-vomiting, or anti-nausea medication is required. Paracetamol is suggested as a mild analgesic in such cases.

Results

In the 282 cases of breast cancers personally collected between March 2019 and December 2022 and retrospectively analyzed according to guidelines [50], 58 were candidates for the "Cut&Sew" technique as they showed advanced (70 years or older) [54–56] age and comorbidities (Tables 1 and 2). Patients were older or super-older, with most primary pT1/pT2 tumors and ductal type cancers, which were distributed in the molecular subtypes as: 37.1 % of Luminal A, 41.5 % and Luminal B (11.2 % HER2 positive. The tumour grade was mostly G2-G3. Mastectomy was performed in 10 patients, whereas quadrantectomy was performed in 48 patients, with most of the tumors localized in Q1.

While accompanied by a relative or a caregiver, all 58 patients belonging to this small retrospective case series acceded the low-invasive surgical technique named "Cut&Sew" under local anesthesia.

There was no intraoperative blood loss, and margins were R0. Negligible pain during surgery was reported in most patients. After the time span between 0 and 10 days post-surgery, no pain was recorded during patient monitoring, which was conducted with or without caregiver support. No post-operative complications or readmissions were documented for the 58 patients described here, and no discomfort or

recurrences were detected during the scheduled breast and oncological visits. Finally, the extent of satisfaction with the overall surgery was collected immediately and corroborated by most patients in the follow-up time, especially regarding the improvement of daily life without breast malignancy.

Discussion

The optimal mode of managing older patients with BC remains a matter of debate in the oncology community. Due to comorbid conditions, high tumour stage, and fair adherence to guidelines, their life expectancy may be largely reduced [1]. Most treatment decisions are made on an individual basis [12,13,57], and approximately one-third of treatment omissions are a result of patient preference [38]. Indeed, the patient's goals for treatment and the potential related risks are equally or even more relevant for older patients than rates of survival [10]. It is possible to allow them access to the ambulatories of the respective hospital centers to search for potential remedies for all difficulties occurring in older patients with breast disease. Even in an ambulatory setting, the pillar of personalized approach for older patients implies the evaluation of the relevant domains in the appraisal of older women with BC, such as comorbidity, mobility/agility, continence, auditory and visual capabilities, activities of daily living, cognition, psychological and emotional states, nutritional status, and familial and social support [8,55,58]. For older patients, combinations of comorbidities portend additional risk beyond single comorbidities, and the associated risk burden is driven by the specific constellation of comorbidities present [59]. Future work must continue to examine the effect of co-occurring diseases to provide personalized and realistic prognostication for older patients undergoing surgery. In a large 12-year time-trend study, multimorbid cancer patients have sustained low access to high volume hospitals for major cancer surgery across many oncologic resections. These results continue to reinforce and highlight the need for policy targeted research and intervention aimed at improving these access gaps

The procedure proposed here was adopted, according to the guide-lines provided to limit SLNB in older women and after a multidisciplinary consensus that addresses the need for this kind of intervention after taking into consideration the age, frailty, and comorbidities extent. Other publications have confirmed the value of ambulatory management due to the high patient satisfaction rate with similar morbidity [23,25–28]. Despite the technique being strictly considered as something that appears very known by surgeons, its application as the "Cut&Sew" approach—that means a short stay (within 3 h) in a destressing context with minimized impact from analgesia—can represent a feasible opportunity for older and frail women who need for a proper geriatric assessment and short-stay surgical programs [6,7,9,14,15,58].

With this technique, local anesthetic infiltration is provided because of its ease of application to avoid more complex and potentially riskier anesthesiologic practices before performing the surgery progressively, step-by-step, cutting the breast, and immediately suturing the skin until complete resection. This could be considered the major novelty of this technique, which is quite common in terms of operative acts but rearranged in a sequence, first providing anesthetic infiltration along the incision line, then applying the mammary resection, which is immediately followed by a suture to organize a surgical overlock-type procedure.

Suturing is the most common method to repair surgical incisions and avoid blood loss. A large population study [61] performed to ascertain whether a tissue adhesive could be an effective alternative to traditional sutures for a large proportion of patients who underwent breast surgery demonstrated that standard wound closure, as applied in this study, provided excellent results. As in such a study, even in the "Cut&Sew" procedure, the good outcomes with absence of infections can be attributed, in part, to the fact that breast surgery is, by definition, a clean procedure [62] and to the fact that with immediate suturing the

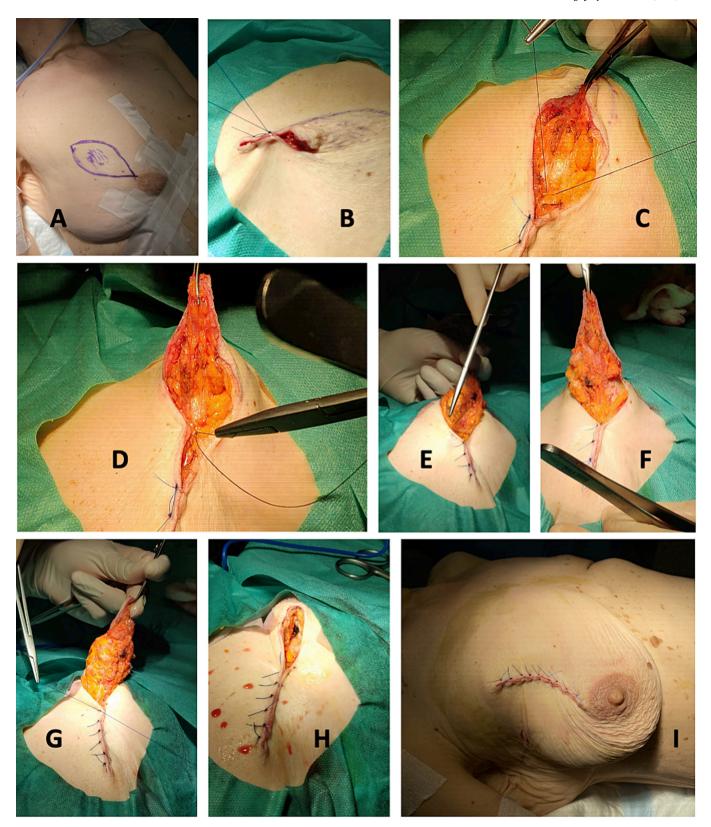


Fig. 1. The surgical procedure sequence of the "Cut&Sew" technique applied to quadrantectomy for treating a ductal G3 carcinoma. A lozenge skin incision was centered on a nodule adhering to the right breast in the external superior quadrant (A, B) along with a wide glandular excision up to the plain fascial (C). Short resection passages of approximately 2 cm immediately followed by suturing continued in a stepwise manner (D, E, F, G, H) till complete resection and wound closure (I).

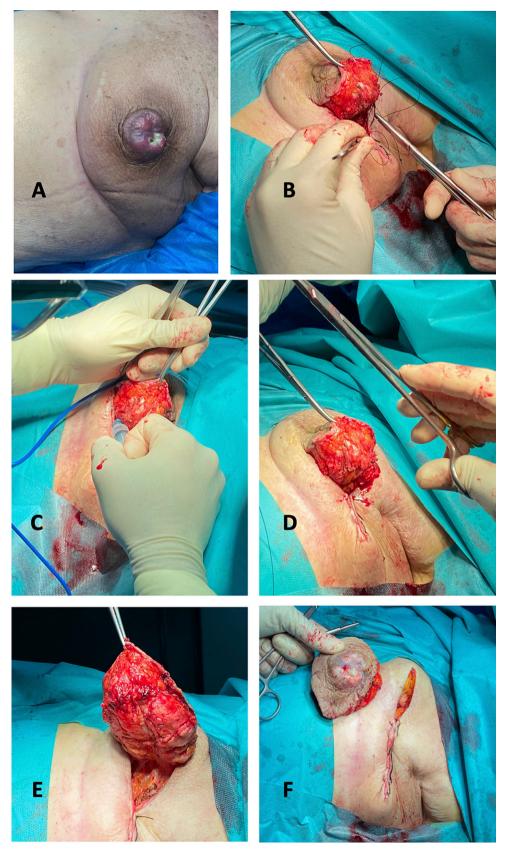


Fig. 2. Surgical procedure sequence using the "Cut&Sew" technique for mastectomy to treat a ductal G3 carcinoma of 40 mm with a skin incision centered on the nipple areola complex (A). After the resection began (B), an injection of anesthetic was provided along the margins (C). Incision was continued following a stepwise suturing (D, E) till the complete detachment of the breast (F).

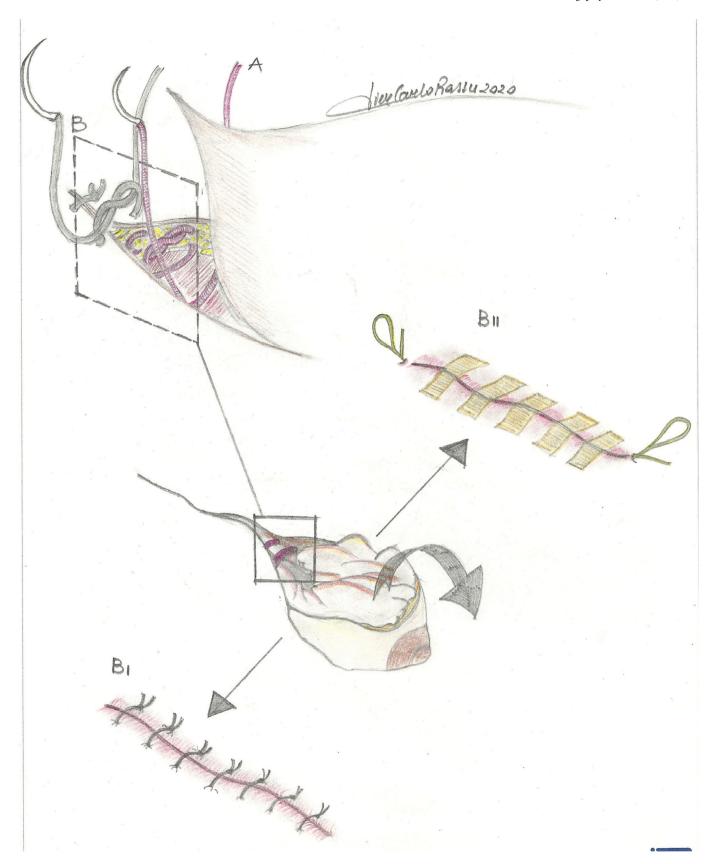


Fig. 3. Details of the "Cut&Sew" technique. Resection with short passages of approximately 2 cm to completely detach the whole breast (A). Suturing of the skin plane with simple stitches or with an absorbable intradermal thread (BI and BII).

Table 1 Mean \pm SD along with number of cases, median value and percentage of frequency measured for parameters from the 58 patients submitted to the Cut&Sew surgery.

Age (years)	81 ± 11
BMI	24 ± 5
Menopausal status	
Pre-menopausal	4 (6.9 %)
Post-menopausal	54 (93.1 %)
Tumour size (mm)	$21\pm10\ (15)$
Tumour staging	
pT1a	2 (3.4 %)
pT1b	2 (3.4 %)
pT1c	21 (36.2 %)
pT2	22 (37.9 %)
pT3	1 (1.7 %)
pT4	5 (8.6 %)
Missing data (5 out of 58)	
Tumour histology	
Ductal	39 (67.2 %)
DCIS	6 (10.3 %)
Lobular	7 (12.1 %)
Other	6 (10.3 %)
Tumour grading	
G1	7 (12.1 %)
G1-G2	0 ()
G2	21 (36.2 %)
G2-G3	1 (1.7 %)
G3	22 (37.9 %)
Missing data (7 out of 58)	
Primary tumour	
Mastectomy	10 (17.2 %)
Multicentric	3 (5.2 %)
Quadrantectomy	48 (82.7 %)
01	15 (31.3 %)
Q2	3 (6.3 %)
Q3	6 (12.5 %)
04	3 (6.3 %)
Q5	8 (16.7 %)
Q6	4 (8.3 %)
Quadrant confluence	9 (18.8 %)
Histopathology	,
Luminal A	17 (37.1 %)
Luminal B with HER2 negative	11 (30.3 %)
Luminal B with HER2 positive	16 (11.2 %)
HER2 enriched	2 (2.2 %)
Basal-like (triple negative)	2 (13.4 %)
Missing data (10 out of 58)	_ (1011 /0)
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Table 2 List of the comorbidities diagnosed among patients treated with the "Cut&Sew" surgery.

Comorbidities

- · Anxiety-depression syndrome
- · Cholecystectomy for lithiasis
- Cognitive impairment
- Diabetes mellitus
- Hypertension
- Hypoacusis
- Hypothyroidism disease
- · Left colic resection for diverticulitis
- Multiple metastatic lesions of liver and bones
- Obstructive chronic pulmonary disease
- · Osteoarthritis of the spine with discopathies
- Osteoporosis
- Previous cerebral ischemia
- · Previous surgery for abdominal hysterectomy for leiomyomata
- Severe cognitive decline
- Stenosis of the spinal canal for osteophytosis
- Urinary incontinence

bleeding and the risk of wood infection are minimized. Yet, immediate suturing allows for shortening the intervention time, which is limited in this "Cut&Sew" approach to 20-25 min. Moreover, the absorbable suture thread does not require further intervention for suture removal, which can be inconvenient for frail patients.

Furthermore, the technique has been designed to overcome the lack of electrosurgical units and, therefore, to reduce the need for hemostasis, which in turn allows for the absence of any drainage, even for major procedures. All these factors positively impact the very short patient discharge (3 h after surgery) with no specific discharge recommendations to explain to the patient, unlike some day-surgery procedures [18,20,24–28,31].

Before discharge, and at a follow-up between 6 and 12 months, the patients were asked to their satisfaction with overall surgery and improvement of their daily life conditions. They were helped by their relatives or caregivers on calling and responding. A specific questionnaire evaluating the grade of satisfaction was not used as well as no questionnaire according to NRS scale has been provided to patients for pain monitoring in order to avoid bias due to unwilling to fill the form, and to keep a warmer human contact with so frail patients. Even if the collection of this information by calling relatives or caregivers might result in an underestimation of adverse events, it was preferred since literature demonstrated that only few people normally complete a voluntary questionnaire, so the attitudes revealed by the questionnaire cannot be considered representative [20]. Moreover, also considering patient frailty, cognitive impairment, and the various comorbidities in this specific group of patients, a direct calling was preferred.

However, the small number of cases collected in this study does not allow for a controlled study, which is necessary to evaluate the safety and efficacy of this technique in association with the approach for frail and older women with comorbidities. Thus, considering the learning curve associated with this technique, it was not explicitly assessed in this series owing to its easy adoption by any advanced breast surgeon. Moreover, a stricter assessment of patient pain and overall satisfaction with the collection of a larger amount of reliable data could allow this technique to be extended to frail and/or older patients as a valuable and safe alternative to the more common hospitalization with general anesthesia. Indeed, outpatient surgery is predicted only when the patient is accurately prepared preoperatively and strictly controlled postoperatively [20,24,26,28-31,34].

Furthermore, as in any ambulatory surgery regimen, costs are minimized compared with those sustained under ordinary hospitalization [25,27,34]. In this light, the "Cut&Sew" technique for frail, older, and super-older patients, falls in the context of a more sustainable surgical management of breast diseases while achieving the primary goal of minimizing the patient's psychological impact experienced in an inpatient surgery [23,24,27].

Conclusion

Patient vulnerability to aging and comorbidities discourages the use of standard surgery. In this light, the described "Cut&Sew" approach might work as the first milestone to adopt breast surgery even when discomfort prevails over the need for intervention, as it is a technique that provides a personalized approach to BC treatment for older and frail patients. Some advantages, such as i) quicker access to surgery than with ordinary hospitalization; ii) a more comfortable and destressing environment for frail and older people affected by breast pathologies; iii) the use of a local anesthetic infiltration and a stepwise cutting-suturing technique that is easy to apply for any advanced breast surgeon; iv) the absence of any drainage that, thanks to the minimal bleeding, allows for a less than 3 h patient discharge; and v) cost minimization if compared to that under an ordinary hospitalization. The aforementioned factor allows this technique to provide treatment de-escalation while avoiding undertreatment for frail, older, and super-older patients with comorbidities for whom the increased operating time and surgical complexity may pose an unjustifiable risk [7,8,10,13,14,54].

Applying the "Cut&Sew" technique on more patients, more standardized data collection, and further planning of controlled studies are needed to establish recurrence-free survival and disease-free survival rates, which limits the robustness of this study as being restricted to the case series treated.

CRediT authorship contribution statement

Pier Carlo Rassu: Conceptualization, Methodology, Writing – review & editing.

Declaration of competing interest

The author reports no proprietary or commercial interests in any production mentioned or concepts discussed in this article. This study received no external financial or non-financial support. There are no additional relationships to disclose. No patents are disclosed. There are no additional activities to disclose.

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Ethical approval

Written informed consent to publish the information presented in this case series was obtained from the patients or their guardians prior to submission. Ethics approval was not required as this case report was deemed not to constitute research, as provided by the Intercompany Ethics Committee of Health Hospital Agencies A.O. of Alessandria, ASL AL., and ASL VC.

Author contribution

The author conceived the work and acquired, analyzed, and interpreted the data. The author drafted the manuscript and approved the final version for publication. The author is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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