Single-port versus conventional multiport access prophylactic laparoscopic bilateral salpingo-oophorectomy in high-risk patients for ovarian cancer: a comparison of surgical outcomes

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Abstract: Bilateral salpingo-oophorectomy (BSO) in carriers of BRCA1 and BRCA2 mutations is widely recommended as part of a risk-reduction strategy for ovarian or breast cancer due to an underlying genetic predisposition. BSO is also performed as a therapeutic intervention for patients with hormone-positive premenopausal breast cancer. BSO may be performed via a minimally invasive approach with the use of three to four 5 mm and/or 12 mm ports inserted through a skin incision. To further reduce the morbidity associated with the placement of multiple port sites and to improve cosmetic outcomes, single-port laparoscopy has been developed with a single access point from the umbilicus. The purpose of this study was to evaluate the surgical outcomes associated with reducing the risks of salpingo-oophorectomy performed in a single port, while comparing multiport laparoscopy in women with a high risk for ovarian cancer. Single-port laparoscopy–BSO is feasible and safe, with favorable surgical and cosmetic outcomes when compared to conventional laparoscopy.

Keywords: prophylactic salpingectomy, single-port access laparoscopy, BRCA carriers

Introduction

Women with BRCA1 or BRCA2 mutations have a 60%–80% cumulative lifetime risk (to 70 years of age) of developing invasive breast cancer and a 15%–65% cumulative lifetime risk of invasive epithelial ovarian cancer.1 Bilateral salpingo-oophorectomy (BSO) in carriers of BRCA1 and BRCA2 mutations is widely recommended to help reduce the risk of ovarian or breast cancer due to an underlying genetic predisposition. BSO is also performed as a therapeutic intervention for patients with hormone-positive premenopausal breast cancer. Preventive oophorectomy has been associated with an 80% reduction in the risk of ovarian, fallopian tube, or peritoneal cancer in BRCA1 or BRCA2 carriers, and a 77% reduction in all-cause mortality.2 Increased knowledge and availability of genetic testing has increased the number of women who are able to identify their risk for the eventual development of breast cancer or ovarian and/or endometrial cancer. This has led many women to consider asking for surgical prophylactic treatment to decrease the potential risk of developing a malignant disease.

The risks and benefits of salpingo-oophorectomy should be weighed, including the degree of protection against cancer and the consequences of induced surgical menopause on health and quality of life.3,4 BSO may be performed via a minimally invasive approach with the use of three to four 5 mm and/or 12 mm ports inserted through skin incisions. To further reduce the morbidity associated with the placement of multiple
port sites, and to improve the cosmetic outcomes, single-port access laparoscopy (SPAL) has played an increasing role in gynecology. Although the feasibility of this procedure has been established, it is still unclear if real advantages exist in performing SPAL versus conventional multiport laparoscopy (MPL). The purpose of this study was to evaluate the surgical outcomes of prophylactic single-port salpingo-oophorectomy compared to conventional MPL in women with a high risk for ovarian cancer.

Materials and methods
This was a prospective, multicentric, case–control study of patients with a high risk for ovarian cancer undergoing a BSO. BSOs were performed between June 2008 and March 2014 in the Division of Obstetrics and Gynecology of Cagliari (a university hospital in Cagliari, Italy), the Division of Gynecology and Obstetrics of Pisa (University of Pisa, Pisa, Italy), the Division of Obstetrics and Gynecology, Ospedale S Chiara (Trento, Italy), and the Division of Obstetrics and Gynecology of Padua (University of Padova, Padua, Italy).

The inclusion criteria were gene-status BRCA1 and BRCA2 carriers and women with hormone-positive premenopausal breast cancer. Cervix cytology and transvaginal sonography evaluations were performed to confirm any suspicion of malignancy, and even the possibility of deep endometriosis. An office diagnostic hysteroscopy with a biopsy ruled out malignancy, and even the possibility of deep endometriosis.

Operative time was defined as the time from umbilical skin incision to completion of skin closure. Postoperative pain intensity was rated at rest using the visual analog scale (VAS). The scale was presented as a 10 cm line, with a verbal descriptor anchored with “no pain” and “worst imaginable pain”. Patients were asked to rate their pain intensity at 6 hours, 12 hours, and 24 hours after surgery.

Patient cosmetic satisfaction was assessed using the Body Image Questionnaire (BIQ) at baseline, 1 week, 4 weeks, and 24 weeks postsurgery. Subjects were asked to complete the BIQ at each visit before seeing their clinician. The BIQ consisted of eight questionnaires in two domains: the Body Image Scale (BIS) and the Cosmetic Scale (CS). Cronbach’s alpha for body image and cosmetic satisfaction were 0.81 and 0.70, respectively. The maximum scores for BIS and CS were 20 and 24, respectively.

A regression modeling analysis was preliminary performed to evidence any significant difference in outcomes among the surgeons of the two groups. The Kolmogorov–Smirnov test was used to evaluate whether values had a Gaussian distribution in order to choose between parametric and nonparametric statistical tests. Comparisons of the proportions and means between groups were done by using the χ² test and independent t-tests, respectively. Statistical differences between repeated measurements were computed using the paired t-test or the Wilcoxon matched pairs test for nonparametric values, both in the case of two comparisons. The analysis of variance for repeated measures and the Friedman test were used for parametric and nonparametric data, respectively. Statistical significance was set at P<0.05.

Surgery
All patients included in the study were admitted to the hospital 1 day before surgery. Standard bowel preparation was indicated, and prophylactic antibiotic therapy (2 g of cefazolin) was administrated 30 minutes preoperatively and again postoperatively. Both SPAL-BSO and MPL-BSO were performed under general endotracheal anesthesia with the patient in the dorsal lithotomy position. A Foley catheter was inserted into the bladder, and then a uterine manipulator was applied. In both procedures, a pelvic washing
and an abdominal exploration were performed. The right
infundibulopelvic ligament was skeletonized and transected
at least 2 cm below the ovarian tissue proper using a 5 mm
ENSEAL® Trio Device (Ethicon, Inc., Somerville, NJ, USA).
The right fallopian tube and mesosalpinx were dissected, and
the utero–ovarian ligament was transected. The same pro-
dure was repeated on the contralateral side. The adnexae
were placed in a 10 mm specimen retrieval bag (ENDOPOUCH®;
Ethicon, Inc.), and the specimens were removed. To prevent
or decrease the occurrence of postsurgical adhesions, 500 mL
of warm lactated Ringer’s solution was instilled in the pelvis
at the end of the procedures.14 The extracted specimens were
sent for histologic examination, and a Foley vesical catheter
was maintained until the morning after surgery.

Hemoglobin concentration was determined in all patients
6 hours after surgery. All patients were permitted sips of
water starting 6 hours after surgery, and a clear liquid diet
was offered as the first meal after passing flatus. If pain
control was needed, 30 mg of ketorolac was administered
intravenously. The patients were encouraged to ambulate
starting the first postoperative day.

All surgical specimens were sent for pathologic evalua-
tion. The ovaries were sectioned along the major axis in order
to produce 2 mm thick sections. The tubes were analyzed
completely and were cut into sections of 2 mm or 3 mm in
transversal thickness. The fimbria, which is known to be the
preferential seat of occurrence of tubal carcinoma, was cut
into longitudinal sections.

Single-port technique
A 2 cm infraumbilical vertical skin incision and a 2–2.5 cm
rectus fasciotomy were performed to enter the peritoneal
cavity, as previously described.15 A reusable single-port
trocar (S-Portal X-Cone; KARL STORZ GmbH & Co.
KG, Tuttlingen, Germany) was inserted into the abdominal
cavity, as previously described. The telescope was made. Three
additional trocars (5–10 mm) were then inserted in the lower
abdominal quadrants under direct laparoscopic vision, as
previously described.16 Specimens were removed through a
soyrapubic incision.

Results
Patient characteristics are shown in Table 1. The surgical
treatment allocation did not determine any withdrawals from
the study. In total, we performed 99 surgical procedures: 49
SPAL-BSO (group A) and 50 MPL-BSO (group B). There
were no differences in the demographic and preoperative
data between the two groups.

Port placement was successful in all patients, and there
were no vascular or visceral injuries, loss of pneumoperi-
toneum, or intraoperative port site bleeding. None of the
patients were converted to a laparotomy. There was no
conversion to MPL or the need for additional ports. No post-
operative complications were observed in either group. The
preliminary regression modeling analysis that was performed
did not yield evidence of any significant difference in the
outcomes among the surgeons in the two groups.

The SPAL-BSO mean operative time was statistically
significantly lower than that of the MPL (35.32±13 minutes
versus 40.02±10 minutes, respectively; \( P<0.001 \)). The time
of entry into the abdominal cavity was significantly lower in
group A (4.15±2 minutes versus 9.12±3.10 minutes, respec-
tively; \( P<0.001 \)), as was the extraction time of the specimens
(1.15±1.5 minutes versus 5.3±3.10 minutes, respectively;
\( P<0.001 \)) (Table 2). Moreover, the SPAL group had a shorter
postoperative hospital stay compared to the conventional
MPL group, but without significance (1.95±0.35 days versus
2.38±0.43 days, respectively; \( P=0.08 \)).

| Characteristics | SPAL (n=49) | MPL (n=50) |
|-----------------|-------------|------------|
| Age, mean (SD), years | 45.30±7.67 | 45.74±8.19 |
| BMI (SD), kg/m² | 23.80±2.2 | 22.22±1.7 |
| Gene status: | | |
| BRCA1 | 30 (61.2%) | 29 (58%) |
| BRCA2 | 15 (30.6%) | 16 (32%) |
| Unknown | 4 (8.2%) | 5 (10%) |
| Breast cancer | 25 (51%) | 28 (56%) |
| Active treatment | 12 (24.5%) | 10 (20%) |
| CBBCS | 4 (8%) | 6 (12%) |

Note: Active treatment = chemotherapy. Abbreviations: SPAL, single-port access laparoscopy; n, number; MPL, multiport
access laparoscopy; SD, standard deviation; BMI, body mass index; CBBCS, concurrent breast cancer surgery (quadrantectomy).

Table 1 Characteristics of the patients
Pain measured immediately after surgery in the recovery unit was lower in the SPAL-BSO group than in the MPL-BSO group. Moreover, postoperative pain scores after 6 hours, 12 hours, and 24 hours were lower in the SPAL-BSO group compared with the MPL-BSO group (Table 2).

The BIS and CS scores at 1 week, 4 weeks, and 24 weeks in the two groups are shown in Figures 1 and 2. At 1 week and 4 weeks after surgery, the mean (± standard deviation) BIS score in the SPAL-BSO group was significantly higher (18.90±0.69 and 19.65±0.54, respectively; P<0.001). At 24 weeks after surgery, the BIS score was still higher in the SPAL-SH group compared with the MPL-BSO group (P<0.001). The CS scores at 1 week and 4 weeks after surgery were also higher in the SPAL-BSO group than in the MPL-BSO group (P<0.001) and the result was maintained at 48 weeks (23.65±1.06 versus 15.71±0.78, respectively; P<0.001).

**Discussion**

Women with mutations in the BRCA1 and BRCA2 gene have a higher risk of developing ovarian cancer, but there are currently no screening protocols for ovarian cancer. Adhesion to strict observation protocols can determine a diagnosis at the earliest stages of the tumor, but it does not affect mortality. The cell of origin of ovarian cancer and the mechanisms by which cancer develops have long been debated. There is mounting evidence that type I and type II ovarian tumors develop independently along different molecular pathways, and that both types develop in the fallopian tube and involve it secondarily. For this reason, patients who are carriers of BRCA mutations are candidates for BSO. The timing for performing BSO is crucial; it should be proposed to women of childbearing age, 35–40 years, who already had or do not wish to have children. Bilateral salpingectomy and delaying

**Table 2 Operative outcomes of SPAL versus MPL**

| Outcomes                        | SPAL-BSO (n=49) | MPL-BSO (n=50) | P-value |
|---------------------------------|-----------------|----------------|---------|
| Operative time (minutes)        | 35.32±13        | 40.02±10       | 0.02    |
| Time to enter the abdominal cavity (minutes) | 4.15±2         | 9.12±3.10      | <0.001  |
| Time to specimen extraction (minutes) | 1.15±1.5       | 5.30±3.10      | <0.001  |
| Length of stay (days)           | 1.95±0.35       | 2.38±0.43      | 0.08    |
| Postoperative complications     | 0 (0%)          | 0 (0%)         | –       |
| Postoperative pain              |                 |                |         |
| Immediately postoperative       | 5.22±0.83       | 8.25±1.12      | <0.001  |
| At 6 hours                      | 5.96±0.73       | 7.88±0.79      | <0.001  |
| At 12 hours                     | 4.65±1.12       | 6.47±0.84      | <0.001  |
| At 24 hours                     | 1.83±0.98       | 3.85±1.12      | <0.001  |

Abbreviations: SPAL, single-port access laparoscopy; MPL, multiport access laparoscopy; SPAL-BSO, single port access laparoscopy-bilateral salpingo-oophorectomy; MPL-BSO, multiport access laparoscopy-bilateral salpingo-oophorectomy.

**Figure 1** Body Image Score at 1 week, 4 weeks, and 24 weeks after surgery.

**Note:** Body Image Score was significantly higher in the SPAL group in comparison to the MPL group at 1 week, 4 weeks, and 24 weeks after surgery, respectively. *P<0.001.

**Abbreviations:** SPAL-BSO, single port access laparoscopy-bilateral salpingo-oophorectomy; MPL-BSO, multiport access laparoscopy-bilateral salpingo-oophorectomy; SPAL, single-port access laparoscopy; MPL, multiport access laparoscopy; BIS, body image score.

**Figure 2** Cosmetic satisfaction at 1 week, 4 weeks, and 24 weeks after surgery.

**Notes:** Cosmetic satisfaction was significantly higher in the SPAL group in comparison to the MPL group at 1 week, 4 weeks, and 24 weeks after surgery, respectively. *P<0.001.

**Abbreviations:** SPAL-BSO, single port access laparoscopy-bilateral salpingo-oophorectomy; MPL-BSO, multiport access laparoscopy-bilateral salpingo-oophorectomy; SPAL, single-port access laparoscopy; MPL, multiport access laparoscopy.
ovariectomy after pregnancy could also be proposed in selected patients.\textsuperscript{19} The decision to undergo surgery is difficult. On the one hand, there is the possibility of neoplastic disease, while on the other hand, patients are faced with the psychological burden of surgical menopause, as well as the risks and cosmetic damage related to the surgery itself. Therapeutic BSO is even frequently proposed in patients previously treated for hormonal-dependent breast carcinoma.\textsuperscript{19}

Open surgery facilitates the intervention by the surgeon; however, recent progress and development in the laparoscopic technique do not indicate its use for this type of surgery. Numerous studies have demonstrated that laparoscopic approaches to various gynecologic oncology conditions, including early-stage endometrial cancer, cervical cancer, and selected pelvic masses, are feasible and result in shorter hospital stays and improved quality of life.\textsuperscript{20,21}

The SPAL is an important development as a new laparoscopic technique.\textsuperscript{5,9} This technique, which is based on reducing the invasiveness and increasing the acceptability and aesthetic results of the classic laparoscopic technique, consists of the introduction of a single-port access system through a natural scar, the umbilicus. This access system accommodates both the instruments and the camera, eliminating the need for multiple separate trocars required by traditional laparoscopic surgery.

One of the major benefits of the SPAL surgery is purportedly the best esthetic outcome. To date, however, there has been no conclusive evidence supporting this,\textsuperscript{22–24} and some studies have not shown any superiority of the single-port access over conventional laparoscopic procedures. Lee et al\textsuperscript{25} demonstrated that SPAL adnexal surgery had comparable operative outcomes to conventional laparoscopic adnexal surgery. In a randomized controlled trial, Song et al\textsuperscript{24} compared cosmetic satisfaction from laparoendoscopic single-site hysterectomy with multiport surgery. The SPAL group reported significantly higher cosmetic satisfaction at 1 week, 4 weeks, and 24 weeks after surgery. Moreover, a recent study evidenced the benefit in relation to body image and cosmesis in SPAL subtotal hysterectomy.\textsuperscript{26} Our study also showed that cosmetic results were significantly higher in the SPAL group compared to the MPL group.

Regarding postoperative pain, Kim et al\textsuperscript{27,28} showed a reduction in postoperative pain scores, but with similar perioperative outcomes with SPAL surgery compared to traditional laparoscopy in adnexal pathology and LAVH. Another randomized controlled trial showed that single-site access provides an advantage over conventional multiaccess laparoscopy in terms of postoperative pain and the need for rescue analgesia, with similar perioperative outcomes.\textsuperscript{29} A meta-analysis by Song et al\textsuperscript{30} that included 331 participants evaluated postoperative pain using a VAS at different time points from the first postoperative day to the day of discharge. The VAS score at 6 hours, 24 hours, and 48 hours postoperatively showed no significant differences between the two techniques.\textsuperscript{30} In our study, we recorded postoperative pain that was significantly lower in the SPAL group than that experienced in the MPL group, as evidenced by lower mean scores on the VAS. The Song et al\textsuperscript{30} meta-analysis showed that the operative time was longer in the SPAL group than in the MPL group, but this difference was not considered to be statistically significant. In our study, we obtained lower operative times with SPAL-BSO compared to MPL. We clearly demonstrated that single-port entry is significantly more rapid than the creation of a pneumoperitoneum and the insertion of an umbilical trocar and 2–3 suprapubic ancillary trocars. Finally, we showed that SPAL surgery offers the advantage of faster and easier extraction of the surgical specimens. In fact, the single access localized at the level of the umbilicus is broader in comparison to those that are performed for traditional laparoscopic surgery. This allows for more rapid and easier extraction, without the need for fragmentation of the surgical specimen and enlargement of the sites of insertion of the trocar; this results in a significantly shorter time than conventional laparoscopy for this phase of the surgery.

Conclusion

SPAL-BSO is feasible and safe with favorable surgical and cosmetic outcomes compared to conventional MPL. The SPAL approach may be ideal for BRCA mutation carriers and breast cancer patients because of its short convalescence, minimal interruption in any ongoing cancer treatment, and the benefits from improved cosmetics and pain. Prospective randomized controlled trials are needed in the future to assess the benefits of SPAL compared to MPL.

Author contributions

All authors contributed toward the data analysis, as well as drafting and revising the paper, and they have agreed to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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