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The challenge of managing isolated STIC lesions: A single-center experience

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ABSTRACT

Objectives: High-grade serous carcinoma (HGSC) arise from serous tubal intraepithelial carcinoma (STIC) lesions, a precursor that develops from the fallopian tube epithelium. Patients with incidental isolated STIC lesions found on salpingectomy specimen have up to 25% risk of developing HGSC or peritoneal carcinomatosis in the future, yet there is no established consensus to guide management.

Methods: This retrospective case series includes patients diagnosed with isolated STIC lesions between April 2017 and January 2024. Patient data was extracted from clinical and pathological databases.

Results: During the study period, 10 patients were diagnosed with an isolated STIC lesion. The fallopian tubes were removed either as part of a hysterectomy for endometrial cancer (n = 3); a prophylactic risk-reducing surgery for *BRCA1* or *BRCA2* mutation (n = 3); or a benign gynecologic condition (n = 4). The median age of the patients was 64 years (range: 53–80). Among patients who underwent genetic testing (n = 9), only three were found to have a deleterious germline mutation in *BRCA1* or *BRCA2*. The patients either received adjuvant chemotherapy (n = 5) or underwent active surveillance (n = 5). One surveillance patient was managed with completion bilateral oophorectomy and omentectomy. Median number of chemotherapy cycles was four (range 4–6 cycles). The median follow-up was 27 months (range: 5–83 months). One patient under active surveillance was diagnosed with peritoneal carcinomatosis 5 years after initial diagnosis of STIC whereas none recurred in the chemotherapy group.

Conclusion: The wide variety of treatment approaches we observed highlights a need for more data on this entity to support management guidelines.

1. Introduction

Serous Tubal Intraepithelial Carcinoma (STIC) lesions are precursor lesions often found in the fallopian tubes of women at high risk for ovarian cancer, such as BRCA mutation carriers. These lesions are the precursor of high-grade serous ovarian carcinoma (HGSC), the most common subtype of ovarian cancer (Kurman and Shih, 2010; Weinberger et al., 2016).

The pathophysiology of STIC progression to HGSC involves several key processes. STIC lesions progress to HGSC either through direct invasive into the underlying tubal mucosa, or more frequently, STIC cells can detach from the fallopian tube surface and spread onto the peritoneal surfaces (Shih et al., 2016). The ovaries are usually the first reported site of metastasis, likely due to their proximity to the fimbriated ends of the fallopian tubes and the favorable environment they provide that promote tumor growth, including enriched blood supply (Shih et al., 2021). Recent studies have shown that the incidence of HGSC or peritoneal carcinomatosis (PC) after a STIC lesion ranges from 7 % to 10.5 % at 5 years, and 20.9 % to 27.5 % at 10 years in BRCA mutation carriers (Linz et al., 2022; Steenbeek et al., 2022). However, these numbers could be lower if all the slides were to be reviewed by expert pathologists, as recent studies have shown that small focus of HGSC can be missed, which may artificially increase the rates of peritoneal carcinomatosis after a STIC lesion (Spenard et al., 2024).

Given the critical role of STIC lesions in the development of HGSC, early and accurate detection using the Sectioning and Extensively Examining the Fimbriae (SEE-FIM) protocol after salpingectomies for benign indications or risk reduction is essential to identify women at

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need of active surveillance or adjuvant treatment (Lee et al., 2006). Diagnosis is achieved through a combination of morphological features and immunohistochemistry including abnormal p53 expression pattern and elevated Ki-67 proliferation index (Shih et al., 2021; Jarboe et al., 2008; Vang et al., 2012).

To date, no standardized management for isolated STIC lesions have been established. While some centres offer reoperation to complete staging with or without adjuvant chemotherapy, others offer active surveillance or administer adjuvant chemotherapy without reoperation. The goal of this study is to examine the experience of a single tertiary care center commonly using adjuvant chemotherapy on the development of ovarian cancer in patients with STIC lesions.

2. Methods

This retrospective case series included patients diagnosed with an isolated STIC lesion between April 1st, 2017, and January 1st, 2024. All surgeries were performed at the same institution. Patients were identified through a review of the institutional research database and additional information was extracted from the electronic medical records (EMR), specifically from pathology reports and clinical records. No broad coded search was used. Patient data were extracted for descriptive statistical analysis. No statistical software was used to generate these analyses. Patients with a prior or concurrent diagnosis of HGSC were excluded. Patients were followed every 6 to 12 months using CA125 as biomarker, clinical exam, and imaging at the discretion of the treating gynecologic oncologist. The pathological examination was performed by a gynecologic pathologist using the SEE-FIM protocol.

Ethical approval was obtained from the research Ethics Board of the institution (McGill University REB project 2022-8522C). The requirement for written informed consent was waived by the REB.

3. Results

A total of ten patients diagnosed with an isolated STIC lesion were included in our study. The fallopian tubes were removed at surgery for endometrial cancer in three patients, as part of prophylactic risk-reducing salpingo-oophorectomy (RRSO) for BRCA1/2 mutation in three patients, and for benign gynecological conditions, such as fibroid uterus, ovarian cyst, and uterovaginal prolapse, in four patients. Seven patients had a hysterectomy and bilateral salpingo-oophorectomy at the time of their primary surgery, two patients had a salpingo-oophorectomy and one patient, whose primary surgery consisted of hysterectomy and bilateral salpingectomy, was re-operated for complete staging, including bilateral oophorectomy and omentectomy. Eight procedures were performed by minimally invasive surgery while the other two were laparotomies. Pelvic washings were performed as part of all surgeries.

The median age for all patient was 64 years (range: 53–80). Three patients were already known to carry deleterious germline mutation, one had a *BRCA1* mutation and two had a *BRCA2* mutation. Of the remainder, six patients were negative for germline *BRCA1* or *BRCA2* mutation, and one patient declined testing. Seven patients reported a family history of cancers, including ovarian, breast, uterine, colorectal, bone, and prostate cancers. Four of the ten patients had preoperative CA-125 testing, with values ranging from 20 to 84 U/mL. One patient had a CA-125 level within the normal range (20U/mL), while three had elevated levels (41, 49, and 84 U/mL); the latter two patients were also diagnosed with endometrial carcinoma (endometrioid carcinoma stage 1A grade 3, carcinosarcoma stage 1A, endometrioid carcinoma stage 1A grade 1). The six patients who did not have preoperative CA-125 testing, were tested after the primary surgery; their values were less than 20 U/mL (range: 6–18 U/mL). STIC lesions were found bilaterally in one patient and unilaterally in nine patients. Immunohistochemistry (IHC) analysis revealed that all patients exhibited abnormal p53 expression, while Ki-67 was found to be increased in eight patients.

All but two patients, who were temporarily lost to follow up after surgery, but later returned for clinical care, were offered adjuvant chemotherapy. Five patients received adjuvant chemotherapy, two declined, and one patient underwent completion oophorectomy and omentectomy. Among the five patients treated with adjuvant chemotherapy, four received a combination of carboplatin and paclitaxel, while one received single-agent carboplatin. One patient receiving adjuvant carboplatin and paclitaxel was also encouraged to receive it given her diagnosis of endometrial carcinosarcoma. Median number of chemotherapy cycles was four (range: 4–6). Neuropathic pain was reported by all treated patients, with three patients found to have grade 1 neuropathy, and the other two had grade 2 to 3 neuropathy. The neuropathy led to a dose reduction of paclitaxel in two patients. Eight patients were followed every 6 to 12 months with CA-125 as biomarker testing. Clinical exam and imaging were left at the discretion of the treating gynecologic oncologist. Overall, the median follow-up was 27 months (range: 5–83 months). One patient, who was lost to follow-up, was diagnosed with PC. At age 56, she underwent RRSO and prophylactic bilateral mastectomy for BRCA2 mutation. At age 61, five years after prophylactic surgery, she presented with hypermetabolic uterine masses, presumed to be fibroids, prompting her to undergo surgery. At the time of surgery, peritoneal carcinomatosis involving the uterus and appendix was identified, and a total abdominal hysterectomy (TAH), along with omentectomy and appendectomy, were performed. Final pathology confirmed a diagnosis of PC, FIGO stage IIIc. After the PC diagnosis, a review of her RRSO slides revealed a unilateral STIC, which had been previously overlooked. She received 6 cycles of carboplatin and paclitaxel. Twelve months after TAH, the patient was alive with no recurrence of disease (Table 1).

Of note, we excluded one case from this series where the initial specimen was interpreted as benign but on subsequent review, following the diagnosis of PC fifteen months later, was revised to HGSC. On review a STIC was diagnosed, and additional sections at that time revealed a small focus of HGSC. The patient had the prophylactic surgery at the age of 65 for a BRCA2 germline mutation, and CA125 levels at that time were 10. She received 6 cycles of carboplatin and paclitaxel. Six months after completion of chemotherapy, the patient was alive on maintenance olaparib with no recurrence of disease.

4. Discussion

We present a clinical review of a series of 10 patients diagnosed with an isolated STIC lesion from a single institution. Management strategies included a combination of surgery and adjuvant chemotherapy, with the only recurrence found in a patient who did not undergo adjuvant chemotherapy. While all 9 patients who were diagnosed with STIC at the time of the resection were offered chemotherapy, re-operation was only necessary for one patient where the ovaries had been left behind during the primary surgery.

At our tertiary-care centre institution, a relatively uniform strategy for managing STIC lesions has been established, which typically includes surgical intervention along with consideration for adjuvant chemotherapy. Conversely, our center does not offer chemotherapy to patients diagnosed with a serous tubal intraepithelial lesion (STIL). For STIC, a significant challenge remains due to the lack of standardized treatment protocols across various institutions. Many centers adopt more conservative approaches, opting for surveillance rather than immediate chemotherapy or completion surgery, which typically includes a bilateral salpingo-oophorectomy, hysterectomy and omental sampling.

Adjuvant chemotherapy may confer potential benefits in the early stages following the diagnosis of STIC by targeting microscopic residual disease that may not be detected during initial surgery, potentially preventing the development of HGSC. A systematic review analyzing 82 BRCA1/2 mutation carriers with isolated STIC identified a recurrence rate of 11 % (4 out of 36) in those who did not undergo surgical staging or adjuvant chemotherapy after initial RRSO. In contrast, no recurrence

Table 1
Characteristics of patients diagnosed with an isolated STIC lesion without an associated tubo-ovarian cancer.

Patient	Age at initial surgery (years)	Menopausal status	Germline testing	Germline status	Indication for initial surgery	Initial surgery	Pathology	Concurrent malignancy	CA-125 (U/mL)	Treatment plan	Completion surgery (if)	Adjuvant therapy (if)	Number of Chemotherapy cycles (if)	HGSC presentation	Follow-up (months)	Outcome at follow-up
1	53	Pre-menopausal	Post-STIC	Negative	Anemia and Menometorrhagia	TLH BS	Bilateral STIC, p53+, Ki67+	_	Preop: n/a Postop: 6	Completion surgery	BO, OMX	_	_	No	22	Alive
2	80	Post-menopausal	Post-STIC	Negative	EIN	TRH BSO, PLND	Unilateral STIC, p53+, Ki67+	Endometrioid endometrial adenocarcinoma stage 1A, gr 1	Preop: 20 Postop: n/a	Surveillance; Declined chemotherapy	_	_	_	No	19	Alive
3	61	Post-menopausal	Post-STIC	Negative	EIN	TAH BSO, PLND, OMX	Unilateral STIC, p53+, Ki67 n/a	Endometrioid endometrial adenocarcinoma stage 1A, gr 3	Preop: 84 Postop: n/a	Adjuvant chemotherapy	_	Carboplatin & Paclitaxel	6	No	7	Alive
4	76	Post-menopausal	Post-STIC	Negative	EIN	TRH BSO, PLND	Unilateral STIC, p53+, Ki67+	Endometrioid endometrial adenocarcinoma stage 1A, gr 1	Preop: 49 Postop: n/a	Surveillance; Declined chemotherapy	_	_	_	No	5	Alive
5	56	Post-menopausal	Post-STIC	Negative	Uterine fibroids	TAH BSO	Unilateral STIC, p53+, Ki67+	_	Preop: n/a Postop: 10	Adjuvant chemotherapy	_	Carboplatin & Paclitaxel	4	No	34	Alive
6	64	Post-menopausal	Post-STIC	Negative	Uterovaginal prolapse	TLVH BSO	Unilateral STIC, p53+, Ki67+	_	Preop: n/a Postop: 12	Adjuvant chemotherapy	_	Carboplatin & Paclitaxel	5	No	83	Alive
7	70	Post-menopausal	Pre-STIC	BRCA1	Prophylactic	LBSO	Unilateral STIC, p53+, Ki67+	_	Preop: n/a Postop: 18	Adjuvant chemotherapy	_	Single agent Carboplatin	6	No	49	Alive
8	59	Post-menopausal	Pre-STIC	BRCA2	Prophylactic	TLH BSO	Unilateral STIC, p53+, Ki67+	_	Preop: 16 Postop: n/a	Adjuvant chemotherapy	_	Carboplatin & Paclitaxel	4	No	27	Alive
9	79	Post-menopausal	_	Unkown	Ovarian cysts	TLH BSO, OMX	Unilateral STIC, p53+, Ki67+	_	Preop: 41 Postop: n/a	Lost to Follow-up	_	_	_	No	72	Alive
10	61	Post-menopausal	Pre-STIC	BRCA2	Prophylactic	LBSO	Unilateral STIC, p53+, Ki67+		Preop: n/a Postop: 14	Lost to Follow-up	_	_	_	Yes	60	Alive

BS: Bilateral salpingectomy; BSO: Bilateral salpingo-oophorectomy; EIN: Endometrial intraepithelial neoplasia; HGSC: High-grade serous carcinoma; OMX: Omentectomy; PLND: Pelvic lymph node dissection; STIC: Serous tubual intraepithelial carcinoma; TAH: total abdominal hysterectomy; TLH: Total laparascopic hysterectomy; TRH: Total robotic hysterectomy; TLVH: Total laparascopic vaginal hysterectomy.

was reported among the 14 patients who either received staging surgery or adjuvant chemotherapy post-STIC diagnosis (Van der Hoeven et al., 2018). A *meta*-analysis looking at RRSO also found that none of the 11 patients treated with adjuvant chemotherapy developed PC over the course of the 96 (range 25–246) months of follow up(Steenbeek et al., 2022). Similarly, Patrono et al. reported a 4.5 % risk of PC in BRCA mutation patients with isolated STIC, with all cases occurring in those who had not received adjuvant chemotherapy at the time of their original diagnosis; specifically, three patients were diagnosed with PC during follow-up periods of 43, 48, and 72 months after RRSO. (Patrono et al., 2015).

Further supporting these findings, a multicenter cohort study led by Spénard and Bernardini on the Canadian management of STIC has provided additional insights into the role of adjuvant chemotherapy (Spenard et al., 2024). In this study, which included 107 patients diagnosed with isolated STIC, 11 patients (10 %) received adjuvant chemotherapy. Notably, none of the patients in the chemotherapy group developed HGSC during the follow-up period, whereas the cumulative incidence of HGSC at 7 years was 20.9 % among the patients who had undergone surveillance or completion surgery(Spenard et al., 2024). However, the study did not find a statistically significant difference between treatment groups, highlighting the necessity for more data to better understand the risks and to establish clearer management guidelines for these patients.

While certain studies support the potential benefits of adjuvant chemotherapy in preventing the progression of STIC to HGSC, its use remains controversial. In two cases recently documented by Stroot and Smit, patients with HGSC achieved complete tumor remission following neoadjuvant chemotherapy, yet their STIC lesions persisted(Stroot et al., 2024). These cases highlight the possible resilience of STIC to chemotherapy, suggesting that the relatively lower proliferation rate of STIC might allow it to evade the effects of chemotherapy, which typically targets rapidly dividing cells. The persistence of STIC despite complete remission elsewhere underscores the need for further investigation into the biological behavior and chemotherapy of STIC to further treatment options.

Interpretation of the literature around the progression of STIC lesions to PC is complicated by the poor interobserver reproducibility of the diagnosis, similarly to other lesions on that diagnostic spectrum: HGSC, serous tubal intraepithelial lesions (STIL), and p53 signatures. As shown briefly in the results, small HGSC can be missed because of the limitations of sampling. This was well demonstrated in the study by Spénard and colleagues, where out of 59 reviewed cases, only 45 (76 %) cases were confirmed to be STIC. Seven (12 %) were revised as HGSC while 3 (5 %) as STIL. Only 2.2 % of centrally confirmed STIC developed HGSC at 6 years(Spenard et al., 2024), suggesting that the reported incidence rates of PC following diagnosis of STIC may be inflated due to underdiagnosis of focal carcinoma in the original specimen.

Recent findings further highlight the complexity of STIC lesions, both morphologically and molecularly. Studies have identified two subtypes of tubal precursor lesions: the BLAD (budding, loosely adherent, detached) and Flat morphologies. BLAD lesions, which are more commonly associated with concurrent HGSC and higher Ki-67 proliferation index, also exhibit genetic alterations like DNA copy number gains at the CCNE1 and CMYC loci, similar to those found in HGSC(Chien et al., 2024). These distinctions suggest that the BLAD subtype may represent a more advanced or aggressive precursor to HGSC, whereas Flat lesions may exhibit a less proliferative phenotype. This heterogeneity suggest even further diagnostic nuances could support different management approaches for isolated STIC lesions.

Adjuvant chemotherapy, while potentially beneficial in reducing the risk of the development of HGSC after identifying an isolated STIC lesion, also comes with significant considerations related to side effects. In this study, the median number of chemotherapy cycles administered was 4, ranging from 4 to 6 across the five patients treated. Neuropathy, particularly associated with carboplatin and paclitaxel, emerged as a notable side effect, often requiring dose adjustments. While such modifications can mitigate discomfort and allow patients to complete their treatment regimen, they also highlight the need to carefully weigh the potential benefits of adjuvant chemotherapy against the quality-of-life impacts related to these side effects. Furthermore, the optimal dosing required to prevent the development of HGSC post-STIC remains uncertain, and patients may require a smaller dosage than currently given, potentially reducing side effects.

This study's limitations include its small sample size and short follow-up timing. The retrospective design also poses challenges in ensuring uniformity in data collection and treatment approaches, potentially leading to variability in patient outcomes. The follow-up period, varying from 5 to 83 months, may not be sufficient to capture late recurrences, especially considering that the average time to HGSC from STIC has been reported to be approximately 6.5 years (1.4–10.7 years) in some studies(Labidi-Galy et al., 2017). As a result, there is a risk of underestimating the long-term implications associated with STIC. Further research with larger, more diverse cohorts and standardized treatment protocols is essential to confirm these findings and refine therapeutic strategies. However, given that these cases are rare, the medical community must rely on small case series and institutional experiences to gather sufficient cases in order to test hypotheses.

5. Conclusion

The findings from this study highlight the critical need for further investigation into the long-term effects and management strategies for STIC lesions. Considering that HGSC typically develops 6.5 years after STIC diagnosis, continued monitoring of this cohort is essential. Upon the diagnosis of STIC, additional sections may be warranted to exclude an associated HGSC. Future research should prioritize identifying features to predict the risk of developing to HGSC after a STIC, optimizing adjuvant therapy strategies, and establishing comprehensive management guidelines for STIC.

Authors' contribution:

RS- Conceptualization, analysis, drafting original manuscript, editing BTC- analysis, writing, review, editing LF- conceptualization, writing review, editing SOAL- writing review, editing XZ- analysis, writing review, RR- writing review, editing VM- conceptualization, writing review, editing LG- conceptualization, writing review, editing LB- Conceptualization, analysis, drafting original manuscript, analysis, editing.

CRediT authorship contribution statement

Renata Sabelli: Writing – review & editing, Writing – original draft, Data curation. **Basile Tessier-Cloutier:** Writing – review & editing, Writing – original draft. **Lili Fu:** Writing – review & editing, Writing – original draft. **Shuk On Annie Leung:** Writing – review & editing, Writing – original draft. **Xing Zeng:** Writing – review & editing, Writing – original draft. **Reitan Ribeiro:** Writing – review & editing, Writing – original draft. **Victoria Mandilaras:** Writing – review & editing, Writing – original draft. **Lucy Gilbert:** Writing – review & editing, Writing – original draft. **Laurence Bernard:** Writing – review & editing, Writing – original draft, Project administration, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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