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Using an evidence-based triage algorithm to reduce 90-day mortality after primary debulking surgery for advanced epithelial ovarian cancer

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HIGHLIGHTS

- Both primary debulking (PDS) & neoadjuvant chemotherapy (NACT) are ideal approaches for different ovarian cancer patients
- Choice between NACT and PDS should be based on risk of surgical morbidity and mortality
- Use of our triage algorithm to choose between PDS and NACT reduces 90 day mortality after PDS
- Use of our triage algorithm also improved residual disease and ability to start chemotherapy within 42 days of surgery.

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ABSTRACT

Objective. To evaluate the impact of an evidence-based triage algorithm to decide between primary debulking surgery (PDS) and neoadjuvant chemotherapy followed by interval debulking surgery (NACT/IDS) for advanced epithelial ovarian cancer (EOC).

Methods. Surgical morbidity and mortality (M/M) after PDS for stage IIIC-IV EOC at Mayo Clinic after implementation of the triage algorithm (contemporary cohort, 2012-July 2016) were compared to that of a historic PDS cohort (2003−2011).

Results. Mean age of the 232 women who met inclusion criteria in the contemporary cohort was 63.9 years. We observed a 71% decrease in 90-day mortality from 8.9% to 2.6% ($P = 0.002$) between the contemporary and historic cohorts. Accordion grade 3+ postoperative complications within 30 days after surgery decreased from 22.3% to 18.3% ($P = 0.19$). Among those with a grade 3+ complication, 90-day mortality rates decreased from 28.3% in the historic cohort to 2.4% in the contemporary cohort ($P < 0.001$) suggesting patients were better able to tolerate complex surgery. When compared to the historic PDS cohort, oncologic outcomes were also improved in the contemporary PDS cohort. Complete as well as optimal (residual disease ≤1 cm) cytoreduction rates increased (45.5% vs. 62.5% and 84.5% vs. 95.3%, respectively, $P < 0.001$), and the proportion of women starting chemotherapy within 42 days of surgery increased (57.4% vs. 69.8%, $P = 0.001$). Three-year overall survival was 53% in the historic cohort and 66% in the contemporary cohort ($P < 0.001$).

Conclusions. Use of the Mayo triage algorithm for EOC was associated with reduced 90-day mortality after PDS and improved oncologic outcomes. Surgical risk assessment is a critical aspect of treatment planning in the primary management of EOC and should be incorporated into practice.

1. Introduction

The management of advanced EOC has been characterized as 'one size fits all' and this applies to surgical management and adjuvant therapy. Primary debulking surgery (PDS) for advanced epithelial ovarian cancer (EOC) is associated with high postoperative morbidity and mortality [1,2]. In a systematic review of randomized clinical trials as well as observational studies (46 studies; 18,597 women), the weighted mean 30-day mortality after PDS was 4.64% (95% CI: 4.6%–4.7%) [3]. Neoadjuvant chemotherapy (NACT) followed by interval debulking (IDS) is an alternate approach with lower postoperative morbidity and mortality [4,5]. For progression-free and overall survival, observational studies have suggested that PDS is superior to NACT [6–9] while randomized trials suggest that NACT is not inferior to PDS [4,5]. These trials have

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been criticized due to the low rates of achieving complete or optimal resection and lower than expected median survival [7]. These trials have indiscriminately included women with varying degrees of fitness for complex surgery. This sets up a false question (dichotomous choice between two options) which on the one hand denies potentially beneficial PDS to some, while on the other hand subjects women for whom evidence has shown will have a high rate of perioperative morbidity/mortality (M/M) to PDS.

The choice between NACT versus PDS in EOC should be directed at ideal application to fit best therapy to the patient/disease. The risk of short-term M/M associated with PDS should be weighed against its survival benefit. Theoretically, aggressive debulking to minimal residual disease with low surgical M/M would yield the best outcomes in EOC. We have previously reported evidence-based risk-prediction models for surgical M/M after PDS [2,10]. Based on predictors in these models, we developed an algorithm (Fig. 1) to identify women at high risk of surgical M/M. Women at high risk of surgical M/M would be triaged to NACT while those not at high risk would proceed with PDS. The triage algorithm was informally introduced in our practice in 2012 for women with advanced EOC. Initially surgeons were using the triage algorithm in a non-uniform fashion with gradual introduction of interval summary reports, and monitoring until full formal implementation in mid-2016. In the current study, we sought to evaluate the impact of our triage algorithm on surgical M/M after PDS prior to its formal implementation, and identify any barriers to implementation or common sources of deviation from the triage algorithm. We hypothesized that surgical M/M after PDS will be reduced with the use of an evidence-based triage algorithm for decision making in advanced EOC thus improving survival outcomes.

2. Methods

This is a single institution cohort study of women who underwent PDS for stage IIIC or IV EOC (including primary peritoneal carcinoma, fallopian tube cancer) at Mayo Clinic Rochester between 1/1/2012 and 7/31/2016. We will refer to these women as the contemporary PDS cohort. Data was obtained from electronic medical record review. Women who underwent surgery without cytoreductive intent (e.g. palliative only) were excluded. Women who did not consent to the use of their medical records for research were also excluded. The study was approved by the Institutional Review Board.

Data on demographics, disease, intraoperative, and postoperative characteristics were abstracted. Postoperative complications within 30 days of surgery were graded using the modified Accordion classification 0–4 scale [11]. When collecting data on complications, procedures that were cancer-related such as paracentesis were not considered. We also collected information on patient- and physician-related factors that may be barriers to triaging high risk women to NACT. Candidate factors included age, race and ethnicity, residency area, and individual surgeon (anonymous).

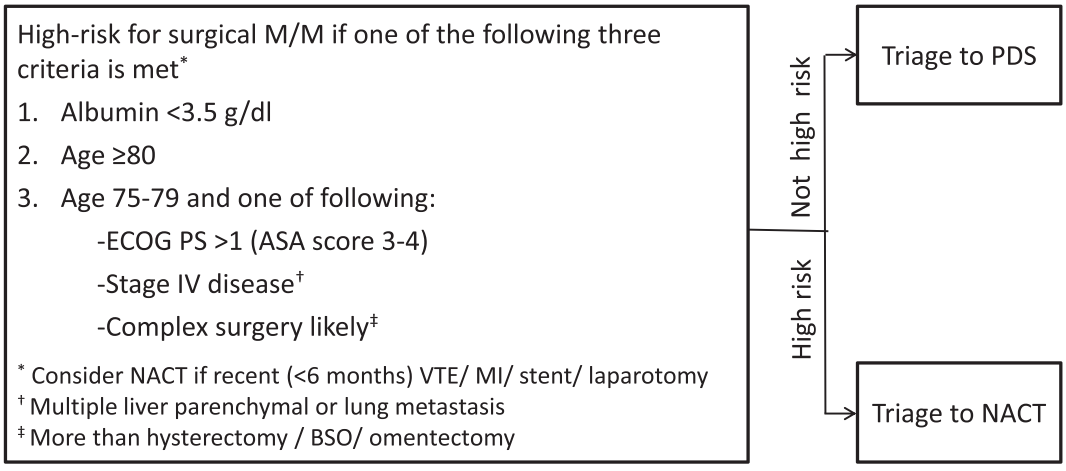
To evaluate the impact of the initial implementation phase of the triage algorithm, we compared rates of Accordion Grade 3+ postoperative complications within 30 days after surgery and 90-day mortality in the contemporary PDS cohort (2012-July 2016) with a historic PDS cohort (2003–2011) used to develop our risk-prediction models. We also evaluated other intraoperative and short-term outcomes such as residual disease after surgery, length of hospital stay, proportion of women never initiating chemotherapy after surgery, and initiation of chemotherapy within 42 days of surgery.

We retrospectively evaluated all women in the contemporary PDS cohort using our triage algorithm (Fig. 1). Women who met triage criteria for high risk yet underwent PDS instead of NACT were placed into the high-risk subgroup. Women who did not meet triage criteria for high risk and underwent PDS in accordance with the triage algorithm were placed into the triage-appropriate subgroup. We evaluated outcomes after PDS in the high-risk subgroup and compared them to the triage-appropriate subgroup. Since these women were retrospectively triaged after undergoing PDS, we used the intraoperative information to determine if they met the definition for "complex surgery likely."

Comparisons between groups were evaluated using the two-sample *t*-test or Wilcoxon rank-sum test for continuous variables and chi-square test or Fisher's exact test for categorical variables. Overall survival restricted to within the first three years following the date of the surgery was estimated using the Kaplan-Meier method and compared between the historic and contemporary PDS cohorts using the log-rank test. P values <0.05 were considered statistically significant. All statistical analyses were performed using the SAS version 9.4 software package (SAS Institute, Inc.; Cary, NC).

3. Results

During the contemporary period (1/2012–7/2016), 232 women underwent PDS and met inclusion criteria. When considering all women undergoing debulking surgery for newly diagnosed advanced EOC during this time period, 68.8% (232/337) were primary debulking



Abbreviations: ASA, American society of Anesthesiologists; BSO, Bilateral salpingo-oophorectomy; ECOG PS, Eastern Cooperative Oncology Group Performance Status; IDS, Interval debulking surgery; MI, Myocardial infarction; M/M, Morbidity and mortality; NACT, Neoadjuvant chemotherapy; PDS, Primary debulking surgery; VTE, Venous thromboembolism.

Fig. 1. The Mayo triage algorithm to predict surgical M/M after PDS.

surgeries and 31.2% (105/337) were interval debulking surgeries. The mean age for the contemporary PDS cohort was 63.9 years (Table 1), and the majority of women had high-grade tumors (94.7%), serous histology (89.2%) and presented with stage IIIC disease (71.1%).

3.1. Improved outcomes after PDS in the contemporary cohort when compared to a historic PDS cohort

Demographic and disease characteristics were comparable between the contemporary and historic PDS cohorts with the exception of preoperative serum albumin testing (Table 1). Compliance with the recommendation for preoperative serum albumin testing improved: 36.5% of the historic cohort had no preoperative albumin available vs. 5.2% of the contemporary cohort. Among those with available serum albumin levels, we observed no difference in the percentage with low albumin levels (<3.5 g/dL). Compared to our historic cohort, median operative time was longer in the contemporary cohort (260 min vs. 315 min, P < 0.001). Surgical outcomes in terms of residual disease (RD) improved in the contemporary cohort. Only 45.5% of the historic cohort achieved complete cytoreduction as compared to 62.5% of women in our contemporary cohort (P < 0.001). The rate of suboptimal debulking (RD >1 cm) decreased (15.5% vs. 4.7%).

We saw some evidence toward improved Accordion grade 3+ postoperative complications within 30 days after surgery (22.3% vs. 18.1%; 18.8% reduction, P = 0.19). Our 90-day mortality rate decreased dramatically from 8.9% to 2.6% (P = 0.002). Among women with an Accordion grade 3+ postoperative complication after PDS, the 90-day mortality was 28.3% in the historic cohort compared to 2.4% in the contemporary cohort (P < 0.001). For women without Accordion grade 3+ postoperative complications, the 90-day mortality was comparable for the two cohorts (3.3% vs. 2.6%, P = 0.64) (Table 2).

Regarding adjuvant therapy we observed a reduction in the fraction of women unable to start chemotherapy (5.8% vs. 2.6%) and a higher proportion starting chemotherapy within 42 days of surgery (57.4% vs. 69.8%, P = 0.001). Three-year overall survival was 53.3% in the historic PDS cohort compared to 66.0% in the contemporary PDS cohort (log-rank P < 0.001). An examination of the Kaplan Meier curves (Fig. 2) reveals a drop shortly after surgery in the historic PDS cohort corresponding to the higher 90-day mortality in that cohort. Among women not known to be deceased at the time of this analysis, 5.1% (17/333) in the historic cohort and 19.6% (31/158) in the contemporary cohort had less than three years of follow-up.

3.2. Short-term outcomes after PDS were better for the triage-appropriate subgroup when compared to the high-risk subgroup

We examined the women in the contemporary PDS cohort upon retrospectively classifying them using the triage algorithm. The high risk women who received PDS instead of NACT were compared to the triage-appropriate subgroup (Table 3). Of the 12 women with missing albumin levels, 11 women did not violate the other triage criteria and were placed into the triage-appropriate subgroup. In addition to being older, a higher proportion of women in the high-risk subgroup had preoperative serum albumin <3.5 g/dL when compared to the triage-appropriate subgroup (58.2% vs. 0%, P < 0.001). They were also twice as likely to undergo low complexity surgery (28.4% vs. 14.5%, P = 0.01), have macroscopic (measurable or suboptimal) residual disease after surgery (56.7% vs. 29.7%, P < 0.001), and stay longer in the hospital (median, 6 vs. 5 days, P = 0.002).

Ninety-day mortality was higher for the high-risk subgroup (6.0% vs. 1.2%, P = 0.06); this difference is clinically significant but failed to reach statistical significance due to low numbers. If the 11 women missing preoperative serum albumin but who did not violate the other triage criteria are excluded due to inability to triage given insufficient information, the 90-day mortality rates would be 0.6% (1/154) for the triage-appropriate subgroup and 6.0% (4/67) for the triage-appropriate subgroup (P = 0.03). Notably, four of the six 90-day deaths in our contemporary PDS cohort could have been potentially averted (or at the very least, died without experiencing the morbidity of surgery) with uniform application of our triage algorithm (Table S1). For every 19 high risk women undergoing PDS, we will have one additional death when compared to PDS for triage-appropriate women only (based on 6.0% vs. 0.6%, number needed to harm = 18.66). Accordion grade 3+ postoperative complications within 30 days after surgery were similar (16.4% vs. 18.8%) and fewer women started chemotherapy within 42 days of surgery (65.7% vs. 71.5%) in the high-risk subgroup compared to the triage-

Table 1
Characteristics and outcomes for women undergoing PDS: historic vs contemporary cohort.

Characteristic	Historic cohort 1/2003–12/2011 N = 620	Contemporary cohort 1/2012–7/2016 N = 232	P[a]
Patient characteristics			
Age (years), mean (SD)	64.6 (11.4)	63.9 (11.1)	0.45
BMI (kg/m^2), mean (SD)	28.3 (6.6)	28.0 (6.1)	0.58
Race			<0.001
White	546 (88.1)	220 (94.8)	
Non-white	17 (2.7)	8 (3.4)	
Not reported	57 (9.2)	4 (1.7)	
ASA score ≥3	295 (47.6)	103 (44.4)	0.41
Preoperative albumin (g/dL)			<0.001
<3.5	88 (14.2)	39 (16.8)	
≥3.5	306 (49.4)	181 (78.0)	
Not available	226 (36.5)	12 (5.2)	
Disease characteristics			
FIGO grade			0.12
1 or 2	30 (4.8)	12 (5.2)	
3	585 (94.4)	214 (92.2)	
Not recorded	5 (0.8)	6 (2.6)	
FIGO stage			0.05
IIIC	481 (77.6)	165 (71.1)	
IV	139 (22.4)	67 (28.9)	
Histology			0.13
Non-serous	92 (14.8)	25 (10.8)	
Serous	528 (85.2)	207 (89.2)	
Operative characteristics			
Surgical complexity			0.12
Low	92 (14.8)	43 (18.5)	
Intermediate	317 (51.1)	126 (54.3)	
High	211 (34.0)	63 (27.2)	
Residual disease			<0.001
Microscopic	282 (45.5)	145 (62.5)	
Measurable (≤1 cm)	242 (39.0)	76 (32.8)	
Suboptimal (>1 cm)	96 (15.5)	11 (4.7)	
Operative time (minutes), median (IQR)	260 (196, 335)	315 (243, 413)	<0.001
Outcomes			
30-Day Accordion Grade 3+ complication	138 (22.3)	42 (18.1)	0.19
90-Day mortality	55 (8.9)	6 (2.6)	0.002
Length of hospital stay (days), median (IQR)	7 (5, 11)	5 (4, 7)	<0.001
Chemotherapy			0.005[§]
No	36[c] (5.8)	6[b] (2.6)	
Yes, started within 42 days	356 (57.4)	162 (69.8)	
Yes, started after 42 days	101 (16.3)	33 (14.2)	
Yes, but start date unknown	57 (9.2)	19 (8.2)	
Unknown	70 (11.3)	12 (5.2)	

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; FIGO, International Federation of Gynecology and Obstetrics; IQR, interquartile range; PDS, primary debulking surgery; SD, standard deviation.
Results are reported as N (%) unless otherwise noted.
[a] Comparisons were evaluated using the two-sample *t*-test for age and BMI, Wilcoxon-rank sum for operative time and length of stay, and the chi-square or Fisher's exact test for all other baseline variables.
[b] 2 not planned, 4 indicated but not received (2 patient declined, 2 patient died).
[c] 1 not planned, 35 indicated but not received (4 patient declined, 9 patient too ill, 22 patient died).
[§] Upon collapsing the 5 levels into 2 levels (Yes, started within 42 days versus all other levels), the P value is 0.001.

Table 2
90-Day mortality after PDS among women with and without Accordion grade 3+ postoperative complications.

90-Day mortality	Historic cohort 1/2003–12/2011	Contemporary cohort 1/2012–7/2016	P[a]
Women with Accordion grade 3+ postoperative complication	39/138 (28.3%)	1/42 (2.4%)	<0.001
Women without Accordion grade 3+ postoperative complication	16/482 (3.3%)	5/190 (2.6%)	0.64

[a] Comparisons were evaluated using the chi-square test.

appropriate subgroup although this difference was not statistically significant. The proportion of women who never started chemotherapy after surgery was comparably low in both groups (3.0% vs. 2.4%).

3.3. Potential barriers to implementation of the triage algorithm

We examined patient- and physician-related factors that may have influenced the decision to proceed with PDS in the triage high-risk subgroup to identify potential barriers to implementation of the triage algorithm. Individual surgeon preference was one of the barriers identified ($P = 0.01$). Among the eight surgeons, the proportion of women who underwent PDS despite being classified as triage high risk ranged from 10.7% (3/28) to 55.0% (11/20) per surgeon. Surgeons were also more likely to choose PDS over NACT for women who were classified as high-risk due to isolated low albumin levels (Table 4). Additional characteristics examined and found to be noncontributory included race, ethnicity, and area of residency.

4. Discussion

In this paper, we describe our initial experience with using an evidence-based triage algorithm for decision making in the treatment of advanced EOC. We found that the initial implementation of the Mayo triage algorithm resulted in a significant decrease in 90-day mortality from 8.9% to 2.6% which represents a 70.8% reduction in deaths. Short-term oncological outcomes were also improved; complete as well as optimal cytoreduction rates increased, the proportion of women never starting chemotherapy decreased, while the proportion of women starting chemotherapy within 42 days of surgery increased when compared to the historic PDS cohort.

Postoperative complications are influenced by a variety of factors including patient anatomy, surgical technique, suboptimal healing, and potentially other random unknown factors, which are difficult to predict. However, an important underlying principle is that women with less 'reserve' whether ascribed to frailty, nutrition or other comorbid conditions will be much more likely to succumb to complications than fit women. This is strongly supported by our findings that despite similar rates of Accordion grade 3+ morbidity in the contemporary cohort, we observed a significantly reduced 90-day mortality and greater likelihood of starting chemotherapy within 42 days of surgery. Additionally, the 90-day mortality after an Accordion grade 3+ postoperative complication decreased from 28.3% in the historic PDS cohort to 2.4% the contemporary PDS cohort. While median length of stay was shorter for our contemporary cohort, this may be related to our ERAS

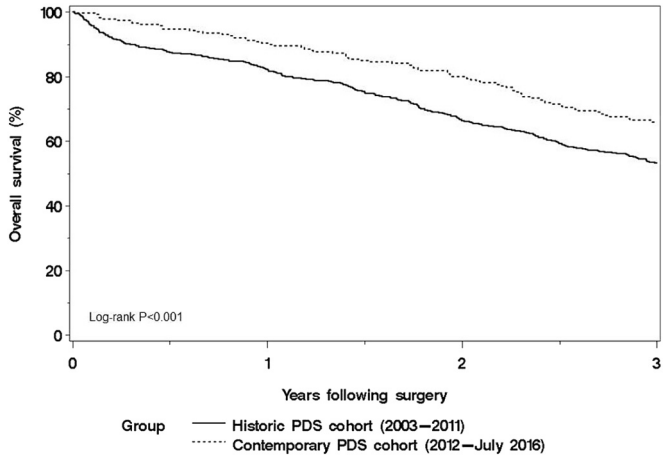


Fig. 2. Overall survival in the contemporary and historic PDS patients.

Table 3
Contemporary PDS cohort: characteristics and outcomes after PDS for the high-risk subgroup as compared to the triage-appropriate subgroup.

Characteristic	High risk subgroup (N = 67)	Triage-appropriate subgroup (N = 165)	P
Patient characteristics			
Age (years), mean (SD)	71.6 (11.0)	60.8 (9.5)	<0.001
BMI (kg/m^2), mean (SD)	27.2 (5.1)	28.3 (6.4)	0.19
Race			0.46
White	62 (92.5)	158 (95.8)	
Non-white	3 (4.5)	5 (3.0)	
Not reported	2 (3.0)	2 (1.2)	
ASA score ≥3	36 (53.7)	67 (40.6)	0.07
Preoperative albumin (g/dL)			<0.001
≥3.5	27 (40.3)	154 (93.3)	
<3.5	39 (58.2)	0 (0.0)	
Not available	1 (1.5)	11 (6.7)	
Disease characteristics			
FIGO grade			0.40
1 or 2	2 (3.0)	10 (6.1)	
3	62 (92.5)	152 (92.1)	
Not recorded	3 (4.5)	3 (1.8)	
FIGO stage			0.60
IIIC	46 (68.7)	119 (72.1)	
IV	21 (31.3)	46 (27.9)	
Histology			0.19
Non-serous	10 (14.9)	15 (9.1)	
Serous	57 (85.1)	150 (90.9)	
Operative characteristics			
Surgical complexity			0.047
Low	19 (28.4)	24 (14.5)	
Intermediate	33 (49.3)	93 (56.4)	
High	15 (22.4)	48 (29.1)	
Residual disease			<0.001
Microscopic	29 (43.3)	116 (70.3)	
Measurable (≤1 cm)	34 (50.7)	42 (25.5)	
Suboptimal (>1 cm)	4 (6.0)	7 (4.2)	
Operative time (minutes), median (IQR)	298 (200, 420)	318 (251, 401)	0.17
Outcomes			
30-Day Accordion Grade 3+ complication	11 (16.4)	31 (18.8)	0.67
90-Day mortality	4 (6.0)	2 (1.2)	0.06
Length of hospital stay (days), median (IQR)	6 (5, 8)	5 (4, 6)	0.002
Chemotherapy			0.82
No	2[b] (3.0)	4[a] (2.4)	
Yes, started within 42 days	44 (65.7)	118 (71.5)	
Yes, started after 42 days	12 (17.9)	21 (12.7)	
Yes, but start date unknown	6 (9.0)	13 (7.9)	
Unknown	3 (4.5)	9 (5.5)	

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; FIGO, International Federation of Gynecology and Obstetrics; IQR, interquartile range; M/M, morbidity and mortality; PDS, primary debulking surgery; SD, standard deviation.
Results are reported as N (%)) unless otherwise noted.
[a] 2 not planned, 2 indicated but not received (1 patient declined, 1 patient died).
[b] 2 indicated but not received (1 patient declined, 1 patient died).

Table 4
Specific triage criteria violated in the high-risk subgroup.

Triage criteria violated	N (% of patients classified as high risk)
Single criterion violated	58/67 (86.6)
Preoperative albumin <3.5 g/dL	30/67 (44.8)
Age ≥80 years	14/67 (20.9)
Age 75–79 years & one of the following:	14/67 (20.9)
ASA score 3–4	
Stage IV disease	
Complex surgery likely[a]	
More than one criterion violated	9/67 (13.4)

Abbreviations: ASA, American Society of Anesthesiologists.
[a] More than hysterectomy, bilateral salpingo-oophorectomy, and omentectomy.

(Enhanced Recovery After Surgery) protocol which was implemented in 2011 [12]. During the triage implementation period (2012-July 2016), the ERAS protocol was applied uniformly. During this period, the triage-appropriate subgroup had a shorter hospital stay when compared to the triage high-risk subgroup even though the high-risk subgroup had twice as many low complexity surgeries. This shorter recovery also supports a better tolerance for complex surgery in the triage-appropriate subgroup.

In addition to risk of surgical M/M, an assessment of cytoreducability (to RD ≤1 cm) is an important consideration in choosing between PDS and NACT. There is no validated tool to predict cytoreducability and this assessment is made by the individual surgeon considering all available clinical information. Our triage algorithm does incorporate stage of disease and surgical complexity which are related to cytoreducability. However, what is considered cytoreducable varies by practice setting, availability of multi-disciplinary surgical support and surgeon experience. In our practice, we first assess if the patient is a candidate for PDS using our triage algorithm. Next, we assess if there is unresectable disease which would be another reason to choose NACT.

Strengths of our approach include an individualized approach of tailoring treatment to each patient based on known risk factors for poor short-term outcomes. Additionally, the variables used in our algorithm are objectively measured, reproducible, and readily available during the course of clinical care. This is in contrast to CT scan based models developed to predict optimal residual disease after PDS, which could not be externally validated. Inter-observer variability in the scoring of the CT scans may have impacted accuracy of these models [13]. Additional strengths of our study include its large sample size, uniform approach to patient care, and inclusion of only advanced EOC. Limitations include a retrospective design and a non-uniform application of our triage algorithm; however we feel that comparison to our historic PDS cohort provides a good context for interpretation of our outcomes. We are currently prospectively following women with advanced EOC and tracking compliance with the triage algorithm after the formal implementation in April 2017 to further evaluate the impact of our selection process prospectively.

In summary, a “one size fits all” approach to advanced EOC may be harming patients. We believe that both NACT and PDS are standard of care approaches for different EOC populations but ideally should be applied using evidence to maximize benefit and reduce harm. Use of the Mayo triage algorithm for decision making reduces 90-day mortality after PDS and improves short-term oncological outcomes such as residual disease and ability to start chemotherapy within 42 days of surgery. While our triage algorithm is yet to be validated in an external setting, the concept of surgical risk assessment has informally been a part of decision making in surgical practice in keeping with the principles of “primum non nocere.” Surgical risk assessment of some manner is a critical aspect of treatment planning in the primary management of EOC and should be incorporated into practice.

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Author's contributions

Study conception and design: William A. Cliby, Deepa Narasimhulu, and Amy L Weaver.

Acquisition of data: Deepa Narasimhulu.

Analysis and interpretation of data: Amy L. Weaver, Michaela E. McGree, and Deepa Narasimhulu.

Drafting of manuscript: Deepa Narasimhulu.

Critical revision: Amanika Kumar, Amy L. Weaver, Carrie L. Langstraat, Michaela E. McGree, and William A. Cliby.

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Declaration of competing interest

None of the authors has any conflicts of interest to declare.

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