

Patient reported Outcomes (PRO) after surgery in advanced Ovarian Cancer – initial results from the international, prospective, multicentre SOCQER 2 study



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Introduction

Patients undergoing surgery for advanced ovarian cancer can undergo a range of procedures, including upper abdominal cytoreduction and bowel resection. Surgery for ovarian cancer is classified according to Pomel¹ and others² into Standard (pelvic surgery), Radical and Ultra-radical/Extensive surgery with extensive surgery incorporating upper abdominal surgery. The impact on patient reported Health Related Quality of Life (PRO) from extensive surgery is poorly understood. Utilization of upper abdominal surgical procedures also varies across centers.



Ethical approvals were obtained for three parallel studies in each country with plans for pooled analysis of results. Participants who met the eligibility criteria i.e. ovarian cancer FIGO stage III-IV, listed for primary debulking surgery or neo-adjuvant chemotherapy with intent of interval debulking surgery, no active treatment for another/secondary cancer in the previous 5 years were invited to

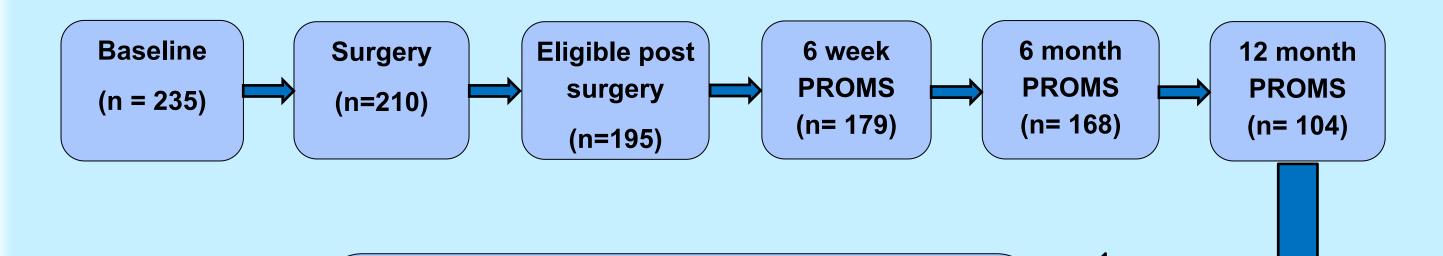
We undertook a multicenter, international, prospective cohort study investigating PRO in women undergoing surgery for advanced ovarian cancer across a range of centers, some of which routinely performed upper abdominal surgeries and others that did not. The study aims to describe PRO measures and surgical outcomes at 14 centres across the United Kingdom, Melbourne (Australia) and

Kolkata (India).

Results

309 patients were recruited across 12 centres in the UK (details below), 1 centre in Kolkata, India (58 recruited, 6 patients found to have low stage disease on surgery were ineligible) and 1 centre in Melbourne, Australia (13 patients recruited and eligible) over 12 months. This poster presents results from the UK centres up to 12 months follow-up and preliminary data from India and Australia. Mean PROM completion rates were 86.8%

Figure 1: UK Patient flow diagram



participate. Participants completed PROMS prior to adjuvant chemotherapy (if applicable), prior to ovarian cancer surgery and at 6 weeks and 6, 12, 18 and 24 months post-surgery to assess quality of life related to ovarian cancer diagnosis.

PROMS included the EQ-5D-5L, EORTC QLQ-C30, OV28, CR29, PR25 at each time point, and the Fear of Progression Scale and Hospital Anxiety and Depression Scale at 12 months only. Clinical characteristics, including survival were captured using Case Report Forms at baseline, surgery, post-operatively and at 18 months post surgery. Surgical complexity scores were calculated for procedures performed as per Alletti.³ Disease load and distribution were captured using preoperative and postoperative Peritoneal Carcinamatosis Index.⁴

Table 1: Clinical characteristics of participants

	-	-	
	UK	Kolkata, India	Melbourne,
	(n=195)	(n=52)	Aust.(n=13)
Age: <50	20	19	*
50-59	43	21	
60-69	70	15	
70-79	62	3	
Median BMI (Kg/m2) [Range]	26 [17 – 45]	27 [18-37]	*
Median Pre-surgery Albumin (g/l) [Range]	40 [13 – 52]	41 [30-49]	41 [27-48]
ECOG Performance status: 0,1 & 2	191	43	13
3 & 4	4	9	0
Upfront Primary Surgery	48	27	8
NACT + Interval Debulking Surgery	147	25	5
Median Peritoneal Carcinomatosis Index	9 [0 – 36]	19 [3-36]	-
(Pre-surgery) [Range]			
Aletti Surgical complexity Scores			
0 – 3	108	5	12
4 – 7	52	17	1
8 & above	33	30	0
Cytoreduction rate (where operable):			
R0 (No gross residual disease)	123	29	1
R1 (Residual disease 0.1 to 10 mm)	52	12	7
R>1 (Residual disease > 10 mm)	19	11	5
Median postop. Hospital Stay (Days)	6 [1 – 69]	7 [3-33] [5 [3-10]
[Range]			
ITU/CCU admissions	69	54	3
Post-operative Complications (Clavien-	60	31	5
Dindo 2,3,4,5)			
Final FIGO stage IIIA/IIIB	21	1	0
IIIC	112	23	9
IV	58	28	4
Not available	4	0	
* To be confirmed			



Withdrawal (n=7)

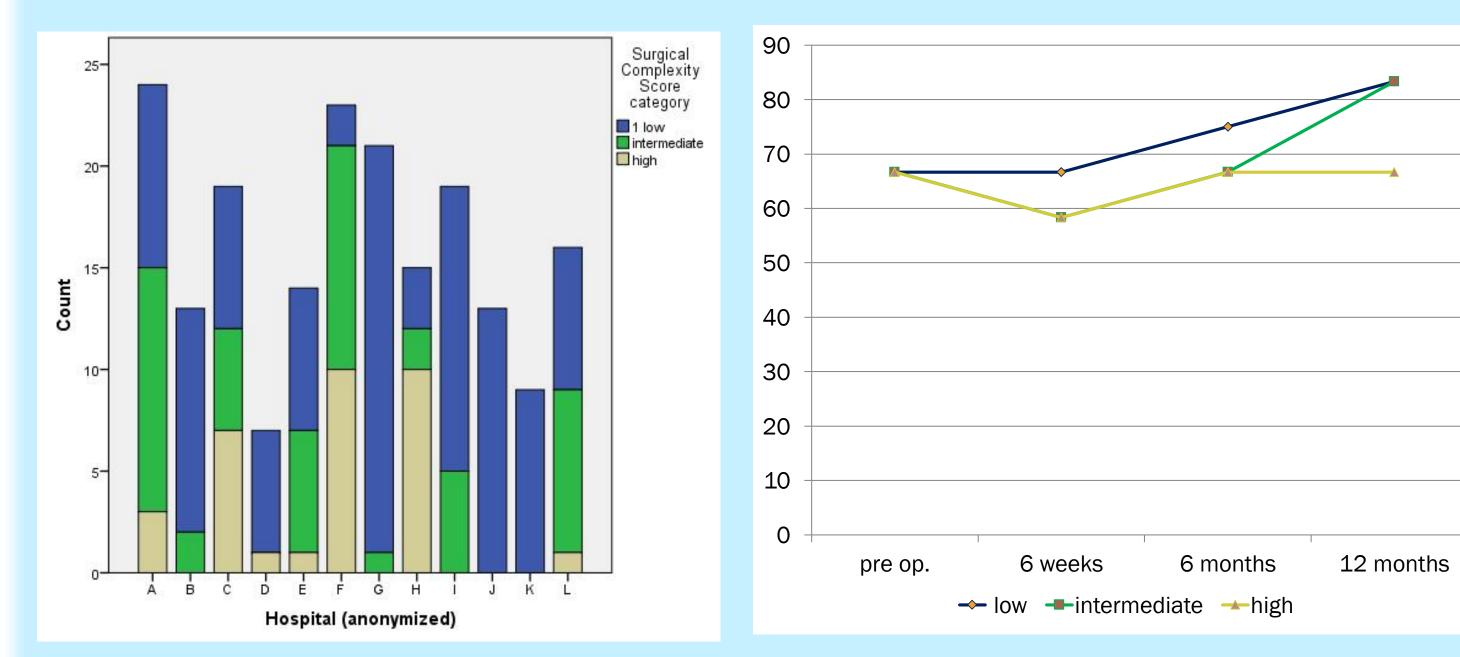
Death (n=19)

Progressive Disease (n=55)

12 month results for UK patients

Fig2. Surgical complexity scores by participating centre

Fig3. EORTC global PRO by Surgical complexity score



Discussion

In an international collaboration, we have prospectively collected data on disease load and distribution at surgery, surgical complexity scores, morbidity, progression, survival and PROMs to better understand the impact of extensive ovarian cancer surgery on quality of life.

The study demonstrates variation in utilization of surgical procedures across centers within the UK and internationally. We have also shown it is feasible to

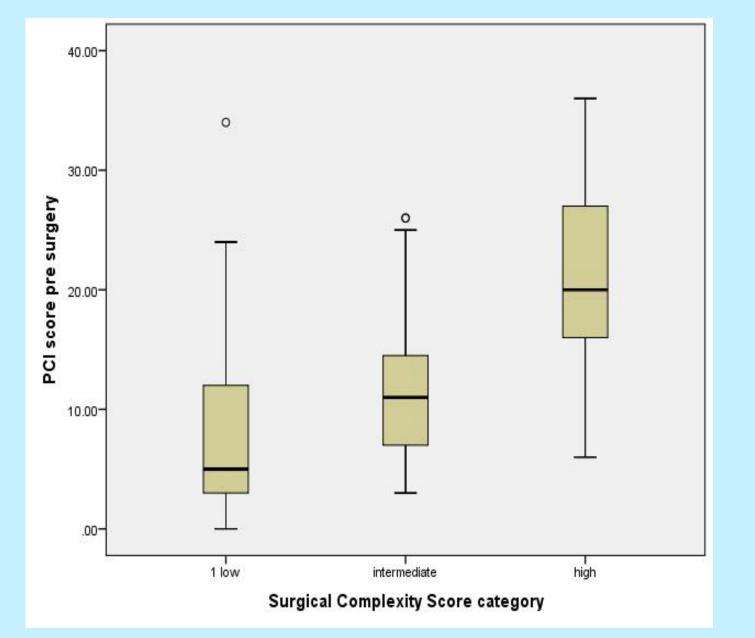


Fig4. Utilisation of surgical procedures by disease load

collect PROMs with high completion rates from patients with ovarian cancer following surgery. Preliminary analysis of UK patients' outcomes showed no association between surgical complexity scores and global health status at 12 months after surgery. Extensive surgery does not result in a decrease of patients' QoL compared to preoperative scores as evaluated by EORTC 30.

Follow-up is ongoing. On completion of data collection, we will relate disease on operation to surgical complexity, progression free survival, survival and quality of life outcomes, describing between centre and country differences.

References

Pomel C, Jeyarajah A, Oram D, et al. Cytoreductive surgery in ovarian cancer. Cancer Imaging. 2007;7(1):210-215.
 NICE, Interventional procedure overview of ultra-radical (extensive) surgery for advanced ovarian cancer. 2013
 Aletti, G.D., et al., Relationship among surgical complexity, short-term morbidity, and overall survival in primary surgery for advanced ovarian cancer. Am.J.Obstet.Gynecol.2007. 197(6): p. 676-677
 Jacquet P, Sugarbaker PH. Clinical research methodologies in diagnosis and staging of patients with peritoneal carcinomatosis. Cancer Treat Res. 1996; 82: 359–374.

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