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

S Sundar1,2, S Kumar1, J Long3, J Balega2, C Fotopoulou2, T Broadhead4, T Duncan2, J Morrison6, J Tidy5, D Kolomainen2, R Manchanda3, R Naik10, R Edmondson11, J Paul12, N Wood13, V Arora14, O McNally14, A Mukhopadayay15, L S Leslie15, C Cummins1


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 Pemel et al. and others 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.

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 centers 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

Table 1: Clinical characteristics of participants

<table>
<thead>
<tr>
<th>Country</th>
<th>UK</th>
<th>Kolkata, India</th>
<th>Melbourne, Australia</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (n=195)</td>
<td>(n=56)</td>
<td>(n=39)</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>56 ± 9</td>
<td>63 ± 9</td>
<td></td>
</tr>
<tr>
<td>M/F</td>
<td>127/68</td>
<td>36/20</td>
<td></td>
</tr>
<tr>
<td>Median BMI (kg/m²)</td>
<td>26 (17–45)</td>
<td>28 (21–38) *</td>
<td></td>
</tr>
<tr>
<td>Median Pre-surgery Albumin (g/l)</td>
<td>40 (33–52)</td>
<td>40 (30–49) *</td>
<td></td>
</tr>
<tr>
<td>ECOG Performance status</td>
<td>19 (6-2)</td>
<td>20 (3-7)</td>
<td></td>
</tr>
</tbody>
</table>
| Upfront Primary Surgery | 4 (0-4) | 3 (0-3) *
| NACT + Initial Debulking Surgery | 147 (117-177) | 145 (98-198) |
| Median Peritoneal Carcinomatosis Index (Pre-surgery) | 9 (4-36) | 9 (3-17) |

Methods

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, invited 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 participate. Participants completed PROMs prior to adjuvant chemotherapy (if applicable), prior to ovarian cancer surgery and at 6 weeks and 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 12 months post surgery. Surgical complexity scores were calculated for procedures performed as per Alleti. Disease load and distribution were captured using preoperative and postoperative Peritoneal Carcinomatosis Index.

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 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

2. NICE, Interventional procedure overview of ultra-radical (extensive) surgery for advanced ovarian cancer. 2013

Funding statement: The UK study was commissioned and funded by the UK National Institute for Health and Care Excellence (NICE) (https://www.nice.org.uk) to inform revision of NICE guidance IP470 on this topic. The views expressed are not necessarily those of NICE.