The modeled CA 125 ELIMination rate constant K (KELIM) scores in predicting outcomes in advanced ovarian cancer undergoing neo-adjuvant chemotherapy and interval debulking surgery

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ABSTRACT:

Objectives

To evaluate the prognostic utility of standardized KELIM score (derived from CA-125 kinetics) in predicting complete cytoreduction at interval debulking surgery (IDS) following neoadjuvant chemotherapy (NACT) in stage III-IV epithelial ovarian cancer patients at BPKMCH Chitwan.

Methodology

Observational study of 46 eligible patients (from 58 total) treated January-December 2025 with carboplatin AUC6 + paclitaxel 175 mg/m² q3w (median 3 cycles). Standardized KELIM calculated using biomarker-kinetics.org calculator (≥1.0 favorable) from serial CA-125 measurements. RECIST 1.1 response assessment, surgical complexity, completeness of cytoreduction (CC0: no gross residual; CC1: <2.5 mm), and postoperative hospital stay was analyzed.

Results

Mean age 59 years (range 29-78); 76% favorable KELIM (mean 1.28, median 1.31, range 0.47-2.22). CA-125 declined from 1498 IU/mL (pre-NACT) to 48 IU/mL (pre-IDS). RECIST: 26% complete response, 70% partial response, 4% stable disease. IDS achieved CC0 in 83% (38/46) and CC1 in 17%—superior to CHORUS (39%), EORTC (81%), SCORPION (77%) trials. Favorable KELIM predicted CC0 with 91% rate (OR 6.1, PPV 94%), simpler surgery (1.35 vs 1.09, p=0.059), and shorter stays (11.9 vs 13.9 days).

Conclusion

KELIM ≥1.0 robustly predicts chemosensitivity and IDS success in advanced ovarian cancer. Favorable scores guide optimal patient selection while unfavorable KELIM identifies candidates for complex surgery, bevacizumab (ICON7/GOG-0218), or HIPEC (Cho et al.). NACT-IDS proves highly effective in high-burden Nepali patients; larger prospective validation needed.

Keywords: KELIM score, Ovarian cancer, Neoadjuvant chemotherapy, Cytoreduction

Introduction

Carcinoma ovary is one of the most lethal malignancies affecting females worldwide. The GLOBOCAN 2022 data from Nepal shows carcinoma ovary as the 10th most common disease as per the incidence with 643 cases and 10th most common as per the death toll with 452 cases among all the cancers while the sheer numbers among female genital malignancies it is second only to carcinoma of cervix in Nepal. The global incidence ranks as the 18th most common disease and 14th most lethal disease as per the GLOBOCAN 2022(1).

Epithelial ovarian cancer (EOC) is a heterogeneous tumor group, with high-grade serous ovarian cancer (HGSOC) as the arche type and main cause of the high fatality rate. The diagnosis is delayed, with 70% of patients diagnosed at an advanced stage (FIGO stages III and IV). The prognosis is poor; with a 5-year overall survival for all stages combined

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being only 20%(2,3). Recently, clinical trials have shown that neoadjuvant chemotherapy (NACT) followed by interval debulking surgery (IDS), is not an inferior treatment course compared to Primary debulking surgery (PDS) for treating advanced-stage ovarian cancer (4–6)A potential advantage of the NACT approach is that it can provide the treating clinician with early information regarding chemotherapy response using clinical, radiological, and tumor markers. Though the response rates for NACT are in the range of 70-80%, majority of these patients will eventually relapse. Upon recurrence, the choice of second line chemotherapy is guided by the duration of response to the prior platinum-based chemotherapy, that is, platinum-free interval (PFI). Several studies of platinum sensitivity have classified groups of patients according to the time to recurrence with the following categories(7):

Between 0 and 6 months (refractory or resistant)

Between 6 and 12 months (partially sensitive)

Beyond 12 months (platinum-sensitive)

The prognosis is poor for patients in platinum-refractory or those whose disease recurs within 6 months (platinum-resistant). In contrast, platinum-sensitive cancers have much better prognosis with a median overall survival of 3 years and a response rate to platinum retreatment between 50% and 70%(7). Actually, controversies and uncertainties still exist in the partially platinum-sensitive population regarding the best treatment and the most effective therapeutic agents, because the response rate to subsequent platinum retreatment has been reported to be only 25-30%. Few recent studies have shown that non-platinum agents could be more effective than platinum-based therapy in this subset of patients(7,8)

An optimal surgical procedure is not always possible for patients with advanced-stage HG-SOC (IIIc to IV) with poor performance status or medical contraindications. Moreover, extensive internal organ resection and major blood loss are associated with a high risk of morbidity(9). Neoadjuvant platinum-based chemotherapy is often performed for patients with advanced ovarian cancer, followed by interval debulking surgery. Surgery is less aggressive, so less morbid, with a similar relapse-free (RFS) and overall survival (OS) compared to standard management (4–6).

Serum cancer antigen 125 (CA125) is the representative tumor marker of ovarian cancer. Different approaches have been used to analyze tumor marker decrease following anticancer treatment (regression coefficient, timing of normalization, nadir concentration) (10). CA 125, the protein encoded by the MUC16 gene, is easily measured, simple to evaluate, and reflective of tumor growth and considered a particularly efficient method to evaluate treatment efficacy(11). Serum CA-125 is elevated at diagnosis in about 85% of ovarian cancer patients(12). The use of neoadjuvant chemotherapy provides a potential window of opportunity to evaluate the true chemosensitivity of tumors and might predict surgical outcome and long-term clinical outcome. Few studies have evaluated whether CA-125 decline during neoadjuvant chemotherapy may predict clinical outcomes in patients with advanced stage ovarian cancer(13–16).

Various kinetic parameters of CA-125 have been evaluated for optimal cytoreduction, platinum resistance, and patient survival. Identifying a patient as either a good or poor responder to treatment can be useful at two levels. First, such a prediction for optimal cytoreduction at IDS may offer better patient counseling by preventing futile surgery. Second, postoperative adjuvant chemotherapy (POAC) could be tailored according to the prediction of platinum resistance. For poor responders, clinical trials with other biologic agents could be applied with molecular profiling instead of conventional chemotherapy(9,17,18).

To reduce the patient's tumor burden and improve therapeutic effect by allowing further surgery, surgeons investigated the possibility of reducing tumor size with two to four cycles of neoadjuvant chemotherapy (NACT). No consensus exists on the optimal timing indicators for interval cytoreduction surgery (IDS) in advanced ovarian cancer. Women who have a high perioperative risk profile or a low likelihood of achieving cytoreduction to <1 cm (ideally to no visible disease) are suggested to receive NACT. Chemotherapy may increase the ratio of patients suitable for IDS; the rates of optimal resection in IDS after induction chemotherapy had been reported to range from 77 to 94%(5,6,9).

A consensus exists that a complete resection of all macroscopic disease (at PDS or IDS) is an independent predictor of progression-free survival (PFS) and overall survival (OS). Tumor load and some specific localization in the abdomen are linked with the feasibility of complete resection. The success of this strategy depends on the level of tumor sensitivity to neoadjuvant chemotherapy(19). Assessment of disease resectability is usually performed at the midpoint of neoadjuvant chemotherapy to consider the feasibility of complete interval surgery. A recent Cochrane review showed that the usefulness of laparoscopy after neoadjuvant chemotherapy remains controversial, because some patients still experience suboptimal surgery despite a laparoscopy predicting complete resection. The performance of computed tomography (CT), positron emission tomography, and magnetic resonance imaging (MRI) in predicting ovarian cancer residual after neoadjuvant chemotherapy were not validated with a strong level of evidence(20). So non-invasive tools to predict the chemosensitivity of the tumor and the feasibility of complete surgery are needed to improve the selection of the best surgical strategy after neoadjuvant chemotherapy.

Monitoring of CA-125 decline during chemotherapy as a predictor of treatment response and as a way to overcome imaging limitations, has been one of the main points of research in ovarian cancer patients. Firstly, the CA-125 nadir level, half-life value and time to nadir have been proposed and secondly, the Gynecologic Cancer Inter Group (GCIG) defined CA125 based response as a 50% reduction in the CA125 level maintained for at least 28 days(21,22). However, both have controversial results and were failed to accurately predict chemosensitivity. Recently, the ELIMination rate constant K (KELIM), a modeled kinetic parameter based on CA-125 measurements during the first 100 days of systemic therapy (adjuvant and neoadjuvant chemotherapy), has emerged as a valuable predictor. It is a mathematical modeling method based not on absolute values of the biomarker, but on the longitudinal kinetics (CA-125 elimination) during treatment, completely independent of renal function(10). Two recent meta-analyses have shown that it is an independent prognostic biomarker for survival outcomes and that can predict chemosensitivity. The higher the KELIM score, the faster the CA-125 elimination, the higher the chemosensitivity and the better the prognosis(13–16,18,19,23,24).

Materials and methods:

It is an observational study carried at the department of gynecological oncology at BPKMCH Chitwan from 1st January 2025 to 31st December 2025.

Inclusion criteria:

Stage III or IV epithelial ovarian cancer deemed unfavorable for primary debulking surgery.

Exclusion criteria:

Multiple primaries, primary debulking surgery, recurrences, other histological types and PROC were excluded from the study.

Patients decided for neoadjuvant treatment were treated with platinum and taxane doublets-carboplatin AUC 6 with Paclitaxel 175mg/m^2 iv every three weekly for 3 cycles and then reassessed at the endo of 3 cycles with imaging using RECIST version 1.1. Serial CA125 measurements were made at the start of chemotherapy and before interval debulking surgery. Imaging studies were done before interval debulking and the categories for complete response, partial response, stable disease and progressive disease were made. The extent of surgery, procedures performed to obtain complete cytoreduction were noted and the level of cytoreduction achieved at interval debulking was made.

KELIM: The modeled CA 125 ELIMination rate constant K (KELIM) calculated during the first 100 chemotherapy days is a validated early marker of tumor chemosensitivity. A minimum of two available CA-125 measurements were required before interval surgery, including a baseline value >25 IU/L, for calculating KELIM. Standard KELIM was calculated using the KELIM calculator provided by at https://www.biomarker-kinetics.org/CA-125 where KELIM is standardized by the prespecified optimized cut-off in the adjuvant setting (cut-off 0.05/days), as a way of providing an easy reading of patient KELIM outcome, with the following equation: standardized KELIM=KELIM estimated by 0.05. KELIM was dichotomized with a prespecified KELIM score: a standardized

KELIM score <1.0 was considered unfavorable and a standardized KELIM score ≥1.0 was considered favorable. The aim of this study is to establish KELIM as prognostic factor for residual disease after interval debulking surgery.

Results:

Analysis of medical records of patients undergoing neoadjuvant chemotherapy followed by interval debulking surgery was done for the last one year at BPKMCH. Total of 58 patients had undergone neoadjuvant treatment and interval debulking surgery in the department of gynecological oncology at BPKMCH. 46 patients among them met the inclusion criterion and were included for analysis.

The patients were middle aged to elderly women with age range of 29-78yrs. The mean age of the cohort is younger than the western benchmark for ovarian cancer (peak 55-64 yrs). Significant proportion of patients were less than 50 yrs (13%), 37% were 50-59yrs and 60-69 years each and 13% were more than 70 yrs older. Moreover, there was no age correlation in regards to KELIM score. Most of the patients were stage IIIC ovarian cancer and only one was stage IIB.

Table 1: Age and KELIM response

Age Group	N	Mean Age	Mean KELIM	RECIST CR %
20-39	2	34	0.82	0%
40-49	4	45	1.28	50%
50-59	12	54	1.35	42%
60-69	17	64	1.37	47%
70+	11	72	1.22	36%

CA125 levels before the initiation of chemotherapy was significantly higher (mean: 1498.5 IU/ml) and mean CA125 before interval debulking surgery was 48.1IU/ml). This demonstrates a good biochemical response to NACT. The mean standard KELIM score was 1.28 (median 1.31, range 0.47-2.22). Favorable KELIM scores were present in 76% of cases (i.e. >1).

The average number of neoadjuvant chemotherapy cycles administered was 3 while few patients received 4 cycles and one patient received 2 cycles of chemotherapy. The patients with fewer chemotherapy cycles had on an average higher value of KELIM as compared to those with more chemotherapy cycles, 1.42vs 1.05).

The response to chemotherapy based on response evaluation criteria to solid tumour version 1.1 (RECIST 1.1) was overall good with majority of patients having a partial response (PR) (32;69.6%) and complete response (CR) (12; 26.1%) and only two with stable disease (SD) (4.3%).

Table 2: RECIST and KELIM comparison

RECIST	Cases	Mean KELIM
CR	11	1.33
PR	33	1.29
SD	2	0.95

Surgical outcome was excellent as the completeness of cytoreduction (CC) was evidenced with most of patients completely cytoreduced to no gross disease and few patients with optimally cytoreduced to residual disease less than 2.5mm in largest diameter as evidenced by CC0 (38;82.6%) and CC1 (8;17.4%) scores. Complex surgical procedures such as bowel resection, radical hysterectomies, parietal peritonectomies were required in a few cases. CC0 cases demonstrated a higher KELIM scores than CC1 cases (1.33 vs 1.04). Favorable KELIM cases achieved CCO in 89%cases (31/35). Favorable KELIM scores predict a 94% positive predictive value for complete cytoreduction.

KELIM values are potentially related to the extent of surgeries as complex procedures such as peritonectomies, ureteric resection anastomosis, bowel surgeries had lower mean KELIM values (1.09) as compared to basic surgeries (1.35).

Table 3: completeness of cytoreduction (CC) and KELIM

Group	N	Mean KELIM
CC0	38	1.33
CC1	8	1.04

Table 4: Extent of surgery and the KELIM

Surgical Extent	Cases	Mean KELIM	P value
Basic (Tah,Bso,Omentectomy)	33	1.35	0.059
Extensive (Parietal Peritonectomies, Ureteric Surgeries, Bowel Resection Anastomosis, Along with Basic Procedures)	11	1.09	

Dichotomizing KELIM into favorable and unfavorable categories with favorable KELIM being more than 1 and unfavorable KELIM being less than 1, the odds of achieving complete cytoreduction in interval debulking was found to be 6.1 times higher in the favorable group.

Table 5: Completeness of cytoreduction and KELIM

KELIM Group	N	CC0 Count	CC0 Rate	Odds CCO
Favorable (>1)	35	32	91%	10.7:1
Unfavorable (≤1)	11	8	64%	1.8:1
Odds Ratio				6.1

Post surgical hospital stay was on an average of 12.7 days which might seem longer but acceptable as the local hospital practice is to discharge after the skin sutures are removed. Though most of our patients had a favorable KELIM scores, higher KELIM scores were associated with shorter hospital stays of 11.9days (KELIM>1.25) as compared to longer hospital stays of 13.9 days (KELIM<1.25) suggesting a better chemotherapy response to shorter hospital stay. Post operative complications were limited to superficial skin infections which were managed accordingly.

So neoadjuvant chemotherapy followed by interval debulking surgery showed an effective strategy in advanced ovarian cancer particularly in patients with high tumor burden, extensive peritoneal disease and poor surgical candidacy for primary debulking. Excellent chemotherapy response was evidenced by favorable KELIM scores in patients showing complete or partial response.

Discussion:

Neoadjuvant chemotherapy and interval debulking surgery is a novel concept in the treatment of carcinoma ovary where research so far have revealed that the approach is non inferior to the time-tested approach of primary debulking surgery followed by adjuvant chemotherapy with patients benefiting from less morbid and less radical surgeries, less post-operative morbidity, equivalent progression free survival and similar overall survival. Our cohort of patients have shown an excellent rate of complete cytoreduction and those not achieving complete cytoreduction were optimally cytoreduced and none of our patient cohort had sub optimal cytoreduction. The evidence of complete cytoreduction is better than the CHORUS trial (NACT vs PDS) which had shown a rate of complete cytoreduction of 39% in the NACT setting(4). The EORTC trial had a complete cytoreduction rate of 80.6% in the NACT setting and ours was better(5). The SCORPION trial had a complete cytoreduction rate of 77% in its NACT arm which is slightly less than the rate of complete cytoreduction achieved by us(6). The response to chemotherapy was also excellent, as evidenced by the rates of partial and complete response according to RECIST 1.1. which is in liaison with the findings of international studies. Such excellent response may be due to the unique tumor biology of the study population as well as meticulous selection process for patients with high tumor burden which needs further research in molecular and genetic aspect of the tumor and patient population.

This study confirms the prognostic value of KELIM in advanced epithelial ovarian cancer in patients treated with neoadjuvant chemotherapy. As an indicator of tumor chemosensitivity, the KELIM value relates to the efficacy of neoadjuvant chemotherapy and impacts the feasibility of subsequent interval surgery. These data are consistent with previous studies. KELIM was shown to be predictive of the likelihood of obtaining complete interval surgery after neoadjuvant chemotherapy in the randomized CHIVA trial(15). KELIM calculated during neoadjuvant chemotherapy may help clinicians to anticipate the feasibility of complete interval surgery. From a surgical point of view, patients exhibiting a favorable KELIM score during neoadjuvant chemotherapy are more likely to present with low tumor burden, leading to an interval surgery with a low complexity score. As a consequence, advanced ovarian cancer patients treated with neoadjuvant chemotherapy, with an unfavorable KELIM, need to be evaluated further to obtain a complete surgery.

Here we observed that both tumor chemosensitivity assessed by a favorable KELIM and the completeness of interval surgery were complementary factors for the success of treatment. Most of our cohort of NACT IDS patients had complete cytoreduction and few had optimal cytoreduction. Those with unfavorable KELIM had higher proportion of residual disease (3/11 vs 3/35). More importantly 8 patients out of 11 who had unfavorable KELIM scores ended up being completely cytoreduced.

Individual reviewing back these cases it was found that they had more tumor load at interval debulking and upper abdominal disease. The prognosis of patients with a favorable KELIM is driven by the chemosensitivity while the prognosis of those with unfavorable is driven by the surgery. An unfavorable KELIM suggested a complex interval surgery to obtain complete cytoreduction as evidenced by the study of Bouvarel et al(14). So KELIM, consistent with a better knowledge of chemosensitivity allows for personalized treatment guiding surgical decision making.

Calculation of KELIM during the NACT might be useful in deciding the novel concept of hyperthermic intra peritoneal chemotherapy during interval debulking. Studies have shown that those patients with unfavorable KELIM scores or those with poor chemosensitivity are ideal for HIPEC once optimally cytoreduced as evidenced by the study of cho et al where there was a significant survival benefit of HIPEC with HR of 0.29(16).

In the era of personalized treatment use of noninvasive tools such as KELIM calculation can help make decisions on use of drugs such as bevacizumab along with regular cytotoxics. As evidenced by the ICON7, where the maximum benefit of bevacizumab was seen in the cohort of patients with high-risk disease having unfavorable KELIM, similar validation study of the GOG 0218 has concluded that bevacizumab should be offered in first line setting in patients with high-risk disease with poor chemosensitivity as evidenced by unfavorable KELIM scores and it could be omitted in patients with favorable KELIM scores(13).

Conclusion:

NACT-IDS proved effective for high-burden advanced ovarian cancer, yielding excellent cytoreduction without suboptimal outcomes. KELIM ≥1.0 robustly indicates chemosensitivity, predicts IDS success, and guides personalized strategies like bevacizumab (benefit in unfavorable cases per ICON7/GOG-0218) or HIPEC (per Cho et al.). Unfavorable KELIM signals complex surgery needs but does not preclude CC0 with aggressive efforts. More prospective validation is required in larger population to generalize the results.

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