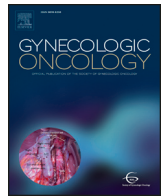




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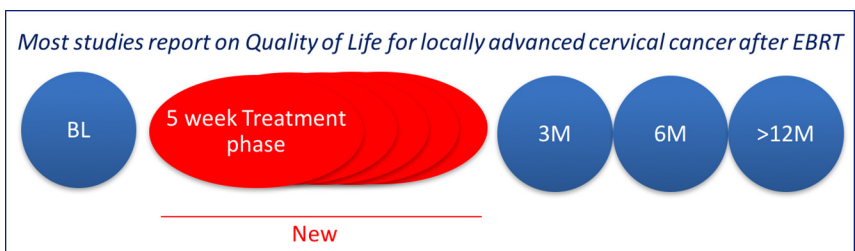
## Dynamics of patient reported quality of life and symptoms in the acute phase of online adaptive external beam radiation therapy for locally advanced cervical cancer

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## HIGHLIGHTS

- Quality of Life and symptoms during IGART for locally advanced cervical cancer
- Lack of prospective patient reported outcomes in acute treatment phase
- Highest symptom levels and impairment at 5th week of treatment
- Diarrhea and dysuria showed most rapid and highest increase in the first 5 weeks.
- End of EBRT (5th week) is most sensitive time point to measure further improvements in IGART.

## GRAPHICAL ABSTRACT



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## ABSTRACT

**Objective.** For locally advanced cervical cancer patients, treated with External Beam Radiotherapy (EBRT), Quality of Life (QoL) questionnaires are frequently used to evaluate treatment-related symptoms and functioning scales. Currently, it is unknown how those evolve during the radiation treatment course. In this prospective study we report on weekly-captured patient-reported QoL and symptoms during image-guided adaptive radiotherapy (IGART) of cervical cancer patients.

**Material and methods.** Between January 2012 and September 2016, all locally advanced cervical cancer patients treated with IGART and brachytherapy with or without chemotherapy or hyperthermia, were eligible. QoL was assessed at baseline; weekly during the first five weeks of treatment; 1 week, 1 and 3 months after treatment, using the EORTC QLQ-C30 and the QLQ-CX24 questionnaires. Comparisons were made with an age-matched norm population.

**Results.** Among the 138 (70%) responders, most symptoms showed a moderate-to-large increase, reaching a maximum at the end of treatment, or first week after treatment with return to baseline value at 3 months after treatment. While most symptoms gradually increased during the first five weeks, diarrhea and bowel cramps already markedly increased within the first three weeks to reach a plateau at the 5th week of treatment. Global health and functioning were temporarily decreased and returned to a plateau at baseline level 3 months after treatment, except for cognitive functioning.

**Conclusion.** A profound impact on QoL was observed during the radiation treatment course, temporarily affecting functioning. The maximum impaired was reached at the end of EBRT.

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## 1. Introduction

Standard treatment for locally advanced cervical cancer is external beam radiation therapy (EBRT) combined with concurrent chemotherapy and brachytherapy. Conformal dose distributions resulting from Intensity Modulated Radiation Therapy (IMRT) or Volumetric Modulated Arc Therapy (VMAT) have markedly reduced dose to organs at risks (OARs), compared to conventional 3D conformal radiotherapy (3DCRT), and less side-effects are reported [1–4]. However, interfraction motion of the uterus and cervix, due to variations in bladder or bowel filling, still necessitates a considerable safety margin. This results in unwanted exposure to OARs, which may translate to more patient reported symptoms and impaired Quality of Life (QoL) [5–8].

Quality of Life questionnaires are a frequent used measurement tool in order to evaluate treatment related symptoms and functioning scales after EBRT for cervical cancer. Many studies report on QoL at baseline and 3 months–5 years after treatment to determine long-side effects [9–14]. However, most of these studies are cross sectional and heterogeneous, including both early stage patients treated with radical surgery and advanced stages treated with definitive radiotherapy. The main conclusion in these studies is that 3 months after treatment most symptoms and functioning scales are returned to baseline value levels again, however, toxicity tends to increase again from one year after treatment. Especially gastro-intestinal, genito-urinary and vaginal/sexual problems, that impact on the Quality of Life (QoL) are of concern [14,15]. Though, despite these studies it is still unknown what the dynamics are during the acute treatment phase and in the intermediate post treatment phase, and which symptoms and functioning scales are most impaired in the first 5 weeks. Furthermore, in those studies data was included from patients treated with conventional 3DCRT, such as a 4-field box technique. Nowadays in many clinics, modern techniques such as image-guided online adaptive radiotherapy (IGART), IMRT, and VMAT have been introduced in order to reduce the dose to OARs. However, the impact these modern techniques have on patient reported QoL has still to be established. Therefore, in order to fill this gap in current literature, the aim of this prospective analysis was to evaluate patient reported QoL and symptoms weekly during treatment to measure the dynamics of the acute phase among locally advanced cervical cancer patients treated with IGART technique using small margins. QoL questionnaires were used from locally advanced cervical cancer patients treated with IGART using a Plan-of-the-Day approach [16]. Main goal of the PotD approach is to reduce toxicity using small margins and online image guidance. Using the QoL questionnaires of the PotD approach, a detailed analysis of the acute phase of the radiation treatment is presented for locally advanced cervical cancer patients treated with a modern radiotherapy technique. Comparisons were made with an age-matched healthy population. In order to facilitate comparisons with literature, we also report our initial results up to one year after treatment.

## 2. Material and methods

From January 2012 onwards, all locally advanced cervical cancer patients who were treated at the Erasmus MC according to a PotD approach were asked to participate in this study and written informed consent was obtained [16]. The questionnaires were part of routine clinical practice and therefore, the hospital local ethics committee granted us a waiver from needing ethical approval for using this data.

### 2.1. Treatment

For all patients, radiotherapy was combined with either chemotherapy or hyperthermia depending on FIGO stage [17]. Patients with small tumors up to FIGO stage IB2 were treated with radiotherapy alone. Patients with higher staged disease received concurrent chemoradiation (5 cycles of cisplatin 40 mg/m<sup>2</sup> body surface). Hyperthermia was

considered if cisplatin was contra-indicated [18]. Patients with very bulky tumors and/or large nodal disease or para-aortic nodal disease received neoadjuvant chemotherapy (cisplatin 70 mg/m<sup>2</sup> body surface, given in 6 six schedules) followed by radiotherapy and hyperthermia.

The PotD approach has been previously described [16]. In brief, four polymer-based markers were implanted during the gynecological

**Table 1**

Patient, tumor and treatment characteristics (n = 138 responders).

	No.	%
Age		
Median, years (range)	51.6	(25–86)
Marital status		
Married	68	48.9
Partner	27	19.4
Single	43	30.9
Children		
Yes	111	80.4
No	27	19.6
Employment		
Employed	81	58.7
Unemployed	37	26.8
Retired	20	14.5
Charlson score/comorbidity <sup>a</sup>		
0	88	63.8
1	38	27.5
2	7	5.1
3	5	3.6
FIGO stage		
1B1	17	12.3
1B2	10	7.2
IIA	7	5.1
IIB	87	63.0
IIIA	3	2.2
IIIB	10	7.2
IVA	2	1.4
IVB	2	1.4
Histological type		
Squamous cell carcinoma	119	86.2
Adenocarcinoma	14	10.1
Other	5	3.6
Brachytherapy first fraction <sup>c</sup>		
Week 4	90	65.2
Week 5	36	26.0
After EBRT	6	4.3
Nodal boost		
Yes	60	43.5
No	78	56.5
Treatment		
CT + RT	74	53.6
NACT + RT + HT	26	18.8
RT + HT	26	18.8
RT alone	12	8.7
Motion <sup>b</sup>		
Mover	44	31.9
Non mover	94	68.1
Treatment position		
Prone	94	68.1
Supine	44	31.9

Abbreviations: CT + RT = chemoradiation (5 weekly courses of cisplatin 40 mg/m<sup>2</sup> body surface), NACT = neoadjuvant chemotherapy (6 courses of cisplatin 70 mg/m<sup>2</sup> body surface) followed by concurrent radiotherapy and hyperthermia, RT + HT = concurrent radiotherapy and hyperthermia, RT alone = radiotherapy alone.

<sup>a</sup> The most frequent co-morbidity was cardiovascular (31.2%) followed by chronic disease (21.7%), COPD (6.5%) and diabetes (6.0%).

<sup>b</sup> Motion: mover: tip of uterus movement of >2.5 cm as measured between a full and empty bladder CT scan

<sup>c</sup> 6 patients received no brachytherapy because of uterus perforation or the tumor was too large.

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