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FALCON

Assessment of the novel online delineation workshop dummy run approach using FALCON within a European multicentre trial in cervical cancer (RAIDs)

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ABSTRACT

Background and purpose: Online delineation workshops (ODW) permit training of geographically dispersed participants. The purpose is to evaluate the methodology of an ODW using FALCON to harmonize delineation within a European multicentre trial on locally advanced cervical cancer (LACC).

Material and methods: Two ODW included 46 clinicians (14 centres). Clinicians completed baseline (C1), guideline (C2) and final contours (C3) for external beam radiotherapy (EBRT) and brachytherapy (BT) for LACC. Interobserver and intraobserver variability was evaluated quantitatively (using the DICE index) and qualitatively compared to expert contours.

Results: Nine clinicians submitted for EBRT and BT for C1–C3. Thirty-two sent any contour. Interobserver quantitative comparisons for EBRT showed significant improvement for C2 vs. C1 for bowel, CTV node, CTV-p and GTV node with significant detriment for GTV node (C3 vs. C1; C2), CTV-p (C3 vs. C2) and bowel (C3 vs. C2), showing in general an improvement in C2 vs. C1, with a detriment in C3 vs. C2 for two target volumes and an organ at risk. For BT there was significant improvement for C2 vs. C1 for bladder, GTV, HR-CTV and IR-CTV, with significant detriment for bladder (C3 vs. C2), thus overall improvement in C2 vs. C1, with only a detriment in C3 vs. C2 for bladder. Centres using MRI imaging for BT contouring did significantly better in the BT case for HR-CTV than those which used other techniques (C2 vs. C1: $p < 0.005$; C3 vs. C1: $p = 0.02$). Intraobserver quantitative comparisons showed significant improvement contouring a region of interest between C2 vs. C1, C3 vs. C1 and C3 vs. C2 for EBRT and between C2 and C1 for BT.

Conclusions: ODW offer training, initial contouring harmonization and allow assessment of centres.

Much has evolved since the first contouring dummy run including distant centres within a multicentre trial, which used CT hard copies [1]. As described in 1995, online education allows participative medical training for geographically dispersed students [2]. Flexibility, essential within e-learning, especially for medical professionals, defined as 'learner control', offers self-task management [3]. Student outcome evaluation is also important, though few report objective internal testing to validate web-based learning tools as a primary outcome [4–7].

Radiotherapy quality assurance has become key to ensure interpretable results within multicentre trials, especially after reports have shown the influence of contouring on patient outcomes [8–11]. Hence the phase III trial of concurrent cisplatin and tirapazamine in head and neck cancer in which when radiotherapy compliance was analysed, a significant reduction of 2 year overall survival and locoregional control was observed when treatment plans were largely deviated from protocol [8].

Proper delineation of target volumes (TV) and organs at risk (OAR) is crucial, allowing optimal oncological treatment and better knowledge of the dose received by surrounding healthy tissue. Thus, several studies have evaluated interobserver and sometimes intraobserver variability between contours [12–15]. Two recent

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reviews addressed this issue, one proposing reporting items for these studies, which this paper will adhere to [16,17]. In locally advanced cervical cancer (LACC) this variability acquires even higher significance. Recent advances in External Beam Radiotherapy (EBRT) and Brachytherapy (BT), namely image guided brachytherapy (IGBT), have shown 3 year local control rates of 92% (tumours > 5 cm) and 98% (tumours 2–5 cm) [18]. This was achieved by applying the Gynaecological GEC-ESTRO (Groupe Européen de Curiethérapie – European Society for Radiotherapy & Oncology) recommendations to the high risk clinical TV (HR-CTV) and dose volume constraints for OAR [19].

The purpose of this study is to validate the methodology of an online delineation workshop (ODW) within a European multicentre prospective study in LACC (Rational molecular Assessments and Innovative Drug Selection: RAIDs), which includes 22 European clinical centres including Eastern and Western Europe [20]. To this aim, participant contours in different periods were reviewed, as well as the participants' personal perception of the knowledge acquired.

Materials and methods

Before the ODW a general questionnaire about LACC radiotherapy was sent to RAIDs centres for input on their practice (Table 1).

ODW structure

Two to four participants from each centre (proportional to the gynaecological team) were enroled in an ODW in LACC, exceeding its capacity, thus two ODW were planned. A technical partnership was established with ESTRO. The methodology was similar to that used in FALCON (Fellowship in Anatomical deLineation and CONtouring) ESTRO ODW [21]. Live presentations were via WebEx and contouring was done using the FALCON EduCase™ contouring platform.

Training was given by an expert, CHM, with one tutor per 10 clinicians. Tutors were radiation oncologists with experience in LACC, trained to use FALCON EduCase™. Live sessions were completed in 3 weeks and participants delineated EBRT (on Computed Tomography: CT) and subsequent BT (on Magnetic Resonance Imaging: MRI) image sets for the same clinical case. The case and image sets with expert contours were chosen with CHM, from the ESTRO FALCON EduCase™ contouring library.

The ODW were held on June–July 2013 and January 2014, respectively, with an identical structure. The first two live sessions were presented by tutors.

- Session 1 exposed FALCON EduCase™ and the clinical case. Participants were informed (orally and in writing) that their contours would be in a study evaluating the ODW, requesting their conformity, which was not revoked. Clinicians had 6 days for baseline contouring (C1, reflecting daily practice).
- Session 2 presented contouring guidelines for EBRT and BT based on the EMBRACE (An intErnational study on MRI guided BRachytherapy in locally Advanced CErvical cancer) protocol, reviewed baseline contours, and included a question-and-answer session. Recommendations from the Gynaecological GEC-ESTRO working group, EMBRACE protocol, a pelvic nodal atlas and two consensus atlases for pelvic normal tissue were sent to clinicians to aid delineation [19,22–25]. They had 2 weeks to modify contours for the same image sets (guideline contouring: C2).
- In session 3 CHM reviewed baseline and guideline contours and held a question-and-answer session.

Lastly, clinicians performed final contouring (C3) for EBRT and BT 1.5–2 months after session 3, to evaluate the long term teaching impact.

Clinical case

A forty-five year old patient with a FIGO IIIB squamous cell CC was studied. Gynaecological exam: large growth (85x50x60 mm) involving the vagina (all fornices 1 cm, anterior vaginal wall 4 cm). The right parametrium had proximal infiltration, the left one until pelvic side wall. Bladder mucosa was not involved. Abdominopelvic CT showed CC with vaginal involvement, enlarged external, internal, lower common iliac, and pre-sacral nodes. No paraaortic nodes. The response to EBRT and concomitant chemotherapy was good: tumour dimensions of 55x40x30 mm, free right parametrium, induration of half of the left parametrium, and involvement of 1 cm of the anterior vaginal wall at the time of BT.

- Volumes required for contouring exercises (at least specified slices for OAR and whole ROI for TV):
  - EBRT:
    - OAR: Bladder, rectum, bowel, sigmoid.
    - GTV-P (gross tumour volume-P): Cervix, parametria and vaginal gross disease.
    - CTV-nodes: Nodal elective volume.
    - GTV node: Radiologically pathological lymph nodes (to boost).
    - CTV-P: GTV-P, uterus and vagina ($\geq$20 mm below GTV-P).
  - BT:
    - OAR: Bladder, rectum, sigmoid.
    - GTV: Macroscopic tumour at BT.
    - HR-CTV: Macroscopic tumour at BT + whole cervix + presumed extra-cervical tumour extension.
    - IR-CTV (intermediate risk CTV): HR CTV + GTV at diagnosis + $\geq$10 mm margin to residual disease at time of brachytherapy towards potential spread.

Contour evaluation methodology

Intraobserver variability was evaluated between C2 vs. C1, C3 vs. C2 and C3 vs. C1, for EBRT and BT treatments, quantitatively and qualitatively.

Interobserver variability was determined quantitatively by analyses centred on regions of interest (ROI) and on years of experience, and for BT also between centres that used MRI-based IGBT and others.

Contours were quantitatively classified by DICE scores [DICE = 2 $\times$ ($Volume_{expert} \cap Volume_{participant}$)/($Volume_{expert}$ + $Volume_{participant}$)] given by FALCON EduCase™ Output [26]:

DICE references for TV [27,28]:

A: Optimal: >0.81
B: Average: 0.65–0.81
C: Suboptimal: <0.65

DICE references for OAR [29]:

A: Optimal: >0.81
B: Suboptimal: $\leq$0.81

In MRI-based brachytherapy for cervical cancer, Dimopoulos et al. defined a range of 0.5–0.7 using the conformity index for target volumes, which when converted to DICE is roughly 62.5–0.81