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PII: S0360-3016(21)02711-5
DOI: https://doi.org/10.1016/j.ijrobp.2021.08.023
Reference: ROB 27239

To appear in: *International Journal of Radiation Oncology, Biology, Physics*

Received date: 23 April 2021
Revised date: 12 August 2021
Accepted date: 15 August 2021

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Running Title: Thecal Sac Contouring for Spine SBRT

Funding: This study was not supported by any source of funding.

Statistical Analyses performed by Robert KOSZTYLA

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Conflict of interest: **A. Sahgal**: Elekta AB; Research Grant. Astra Zeneca, Varian (CNS Teaching Faculty), BrainLAB, Medtronic Kyphon; Honoraria. Varian; Medical Advisory Group, Elekta; Gamma Knife Icon. Brain LAB; Advisory/Consultant. International Society of Stereotactic Radiosurgery member (ISRS) and co-chair (AO Spine KFT). **S.S. Lo**: Elekta ICON Expert Group; Member. Radiosurgery Society Entity: Non-Profit Professional Organization; Member of Board of Directors and Medical Director of the Distinction in Practice in Stereotactic Radiotherapy Accreditation Program Role, Promotion of SRS and ABRT. American College of Radiology (CARROS, Radiation Oncology

Chapter), past president. **A.Bergman**: Canadian Cancer Society Innovation to Impact**;** Research Grant, **R. Kosztyla**: BC Association of Medical Physicists (past president). **N. Dea**: Consulting: Stryker, Medtronic. Stock, Medtronic **S.T. Chao:** Varian Medical System, personal fees Research Support Blue Earth Diagnostics. **E.L. Chang**: CNS Scientific Programme Committee Track Member; ASCO. **U-K. Chang**: President; Korea Spinal Oncology Research Society **K.J. Redmond**: Accuray: research funding, honorarium for speaking engagement, travel expenses Brainlab: travel expenses BioMimetix: Data safety monitoring board Elekta: research funding, travel expenses NCCN: honorarium for speaking engagement. **S.G. Soltys**: Consultant; Inovio Pharmaceuticals, Inc. Zap Surgical Inc, speakers' bureau. **E.M.Dunne**, **S. Faruqi, A. J. Ghia** and **M. Liu** have no disclosures to report.

<u>Research data are not available at this time</u>

Abstract

Purpose: To present inter observer variability (IOV) in thecal sac (TS) delineation based on contours generated by eight experienced spine stereotactic body radiotherapy (SBRT) radiation oncologists, and propose contouring recommendations to standardize practice.

Methods and materials: In the setting of a larger contouring study that reported target volume delineation guidelines specific to sacral metastases, eight academically based radiation oncologists (RO) with dedicated spine SBRT programs independently contoured the TS as a surrogate for the cauda equina and intra-canal spinal nerve roots. Uniform treatment planning simulation CT datasets fused with T1, T2 and T1 post gadolinium magnetic resonance imaging (MRI) for each case were distributed to each RO. All contours were analysed and agreement was calculated using both Dice Similarity Coefficient (DSC) and simultaneous truth and performance level estimation (STAPLE) with kappa statistics.

Results: A fair level of STAPLE agreement was observed between practitioners according to a mean kappa agreement of 0.38 (range, 0.21 – 0.55) and the mean DSC (± standard deviation; with range) was 0.43 (0.36 ± 0.1 – 0.53 ± 0.1). Recommendations for a reference TS contour, accounting for the variations in practice observed in this study, include: contouring the TS to encompass all the intra-thecal spinal nerve roots and, caudal to the termination of the TS, the bony canal can be contoured as a surrogate for the extra thecal nerves roots that run within it.

Conclusion: This study shows that even amongst high volume practitioners, there is a lack of uniformity when contouring the TS. Further modifications may be required once dosimetric data on nerve tolerance to ablative doses, and pattern of failure analyses of clinical datasets utilizing these recommendations, become available. The contouring recommendations were designed as a guide to enable consistent and safe contouring across general practice.

Introduction

The cauda equina, and intra-canal spinal nerve roots distal to the natural tapering of the true thecal sac, are major dose limiting organs-at-risk (OAR) for spinal stereotactic body radiation therapy (SBRT) practice, due to the risk of radiation damage that can lead to paralysis and loss of bladder and bowel function. Typically, the thecal sac (TS) has been the surrogate contour due to the inability to accurately contour individual nerve roots. Several challenges exist in this approach such that over-estimating the TS contour could limit the dose exposed to adjacent disease, in particular, the concern is in under-dosing epidural space which has been observed as the most common site of local failure (1-3). Conversely, under-estimating the TS contour could inadvertently increase the dose to the cauda equina and intra-canal spinal nerve roots (4 - 7) which can increase the risk of serious adverse events associated with central neuropathy. At present, TS contouring is a standard of care and applied to clinical trial design and, therefore, an accurate understanding of contouring the TS is imperative for safe practice (8,9). Currently there is no reported reference, or a gold standard contouring approach, describing the TS contour specific to spine SBRT practice.

Materials and Methods

In the setting of a larger contouring study that reported target volume delineation guidelines specific to sacral metastases (10), eight highly experienced radiation oncologists (RO) with dedicated spine SBRT programs participated in this TS contouring sub-study. Herein, we present the inter observer variability (IOV) in TS delineation observed.

RO's were provided with 10 cases of metastatic disease to the sacrum and asked to independently contour the TS, or a surrogate such as the cauda equina or sacral canal, in accordance with their regular practice. Details of each case are provided in Table 1. Further information, including radiographic images for each case, has been previously published (10). In order to quantify multi-institutional and multi-observer variability, participants were not provided with instructions on how to delineate the volume. Each RO was provided a treatment planning simulation computer tomography (CT) data set fused with T1, T2 and T1 post gadolinium magnetic resonance imaging (MRI) for each case. Axial T1 3D fast field echo (FFE) and axial T2 3D turbo field echo (TFE) MRI sequences (voxels: 1x1x2 mm for both sequences) were used. The fusion accuracy was verified at each institution by a physicist and confirmed by the physician. Both the CT and MR imaging were obtained as thin slice acquisitions in accordance with the SPIne response assessment in Neuro-Oncology (SPINO) guidelines (9). Practitioners were additionally asked exploratory questions including the specific dose/fractionation they apply to the TS below the level of the spinal cord.

The completed volumes were collected in DICOM format. Contours were imported using an in-house code developed in MATLAB (version 8.1.0.604 - The MathWorks, Inc., Natick, MA). The variation between expert contours was analysed using both the Dice Similarity Coefficient (DSC) and Simultaneous Truth And Performance Level Estimation (STAPLE) method. Kappa statistics estimated overall agreement and corrected for the possibility that contours agreed by chance alone (11,12). Specificity values were defined as the relative frequency that an observer does not include a voxel when it is outside the consensus volume while sensitivity values were defined as the probability that a voxel in the consensus contour is also in each of the expert contours.

Results

TS delineation

In total, 71 TS contours were returned by the eight RO. There was a median of seven TS contours per case (range, 6-8) (Table 1). Five RO contoured the TS as an independent structure to the sacral plexus/nerve root structure, while the remaining RO combined both structures in to one volume. It was the practice of the majority to contour the TS as all contents within the dural envelope, while three of the eight contributors contoured the bony sacral canal or individual nerves within the cauda equina as a surrogate for the TS.

In only 19/71 TS contours did the caudal slice of the experts' TS contour correspond with the radiological determination of the actual termination of the TS. Although in 33/71 cases, the caudal slice of the TS corresponded to the vertebral body in which the TS terminated.

Figure 1 demonstrates each experts' individual TS contour (variety of colours) on selected axial T2 MRI slices with the recommended consensus TS contour overlaid in red.

IOV metrics

Table 2 summarises the metrics of IOV in contouring the TS for each of the 10 cases. There was a fair level of STAPLE agreement between practitioners with respect to their TS contour, with a mean kappa agreement of 0.38 (range, 0.21 – 0.55). The mean DSC (± standard deviation; with range) was 0.43 ± 0.0 (0.36 ± 0.1 – 0.53 ± 0.1).

Dose/Fractionation applied to the TS

The answer to exploratory questions on what dose/fractionation is applied to the TS below the level of the spina cord varied between institutions which is unsurprising given the paucity of data in the literature to guide practice. The median dose/fraction for cases treated in one, two and three fractions was 16 Gy (range, 16 – 20.5 Gy), 17 Gy (range, 17 – 22 Gy) and 18 Gy (range, 18 – 27.5 Gy) respectively. We would suggest adhering to current spine SBRT trial protocols which have set the TS/cauda equina dose constraint at 16 Gy in 1 fraction with a D5 cc ≤ 14 Gy (RTOG 0631) and a Dmax of ≤17 Gy in 2 fractions (SC-24 trial) (8, 13), otherwise, typically those constraints applied to the spinal cord constraint are applied to the TS.

Generating a consensus contour

When STAPLE contours were generated (using an 80% confidence level) they did not make anatomical sense, perhaps unsurprising given the low level of agreement on analysis. Recognising the limited applicability of the generated STAPLE contour to an anatomically appropriate TS contour, consensus recommendations on how to contour the TS were generated following discussion amongst all experts. These discussions involved recognition of the variation in practice that exists and addressed specific issues such as the extension of the TS contour beyond its anatomical termination. These recommendations are detailed in Table 3 with selected T2 MRI axial slice illustrations provided in Figure 2.

Discussion

This study shows that even amongst high volume practitioners, there is a lack of uniformity when contouring the TS. This is concerning given the influence the TS has on plan assessment and determining the dose delivered to disease. Given the increased use of spine SBRT worldwide, especially within the context of positive clinical trials such as the SC-24 and the SABR-COMET trials, consistency is crucial for safe and reliable practice (8,14), and to determine tolerance as data matures.

It is recognized that contouring the TS is challenging, and more so than the spinal cord where the anatomy is defined. Accurate delineation of the TS depends on an in-depth knowledge of the anatomy and function of the intra- and extra-thecal organization of the central and peripheral nerves. The cauda equina lies within the cerebral spinal fluid (CSF) in the subarachnoid space. The three-dimensional organization of the intrathecal nerves within the cauda has not been well documented as disorganization of the spatial relationship of the nerves is known to occur during cadaveric preparation/cauda equina fixation or when the dura is breached resulting in loss of CSF. Although it is possible to identify individual nerves using MRI, their location is both patient and position dependent (15-17). In addition, the movement of the nerves associated with CSF pulsation within the TS cannot be accurately visualized given the limits of MR cine imaging resolution. As such we recommend contouring the TS to encompass all the intra-thecal spinal nerves. Caudal to the termination of the TS, we recommend contouring the bony canal as a surrogate for the extra thecal nerves that run through it until dosimetric data become available on nerve tolerance to ablation.

We recognize that the proposed structure includes the area within the bony canal caudal to termination of the TS, and technically the entire structure could be labelled 'cauda equina nerve roots' to describe exactly what the structure encompasses. However, to be consistent with prior literature and trial protocols, we suggest continuing to call the entire structure the TS. Once further dosimetric data on the tolerance of nerve roots to ablation becomes available, further modifications can be made to appropriately separate the true TS from the nerve roots.

There will, however, be caveats to this approach where individual judgement will need to be applied. For example, in cases where gross disease abuts the TS, practitioners may wish to delineate a more conformal volume encompassing the nerves themselves. The authors recognize that the proposed recommendations summarized in Table 3 are not based on pattern of progression analysis or dosimetric analysis of cauda equina or nerve root toxicity, and designed as a guide for consistent and safe contouring of the TS across general practice.

Conclusion

In the present era where targeted and immunotherapies are resulting in increased disease-free-survival, and potential cure for a subset of patients with metastatic disease, the practice of spine SBRT will only continue to escalate globally. Although spinal cord contouring has been well described with safe dose limits for clinical practice by the recent HYTEC spinal cord NTCP analyses (18), there exists a gap with respect to standardizing practice for those metastases caudal to T11 where the cauda equina emerges as the dose limiting OAR. We present consensus contouring recommendations for the TS accounting for variations in practice according to a group of high-volume expert practitioners to guide safe and consistent practice.

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Figure 1

Selected sagittal and axial T2 MRI slices through the sacral spine. Individual physician thecal sac (TS) contours are depicted in different colours with the consensus TS contour overlaid in red. Axial images of the sacral spine in a craniocaudal direction are represented by images b (S1), c (S1), d (S2), e (S3) and f (S4).

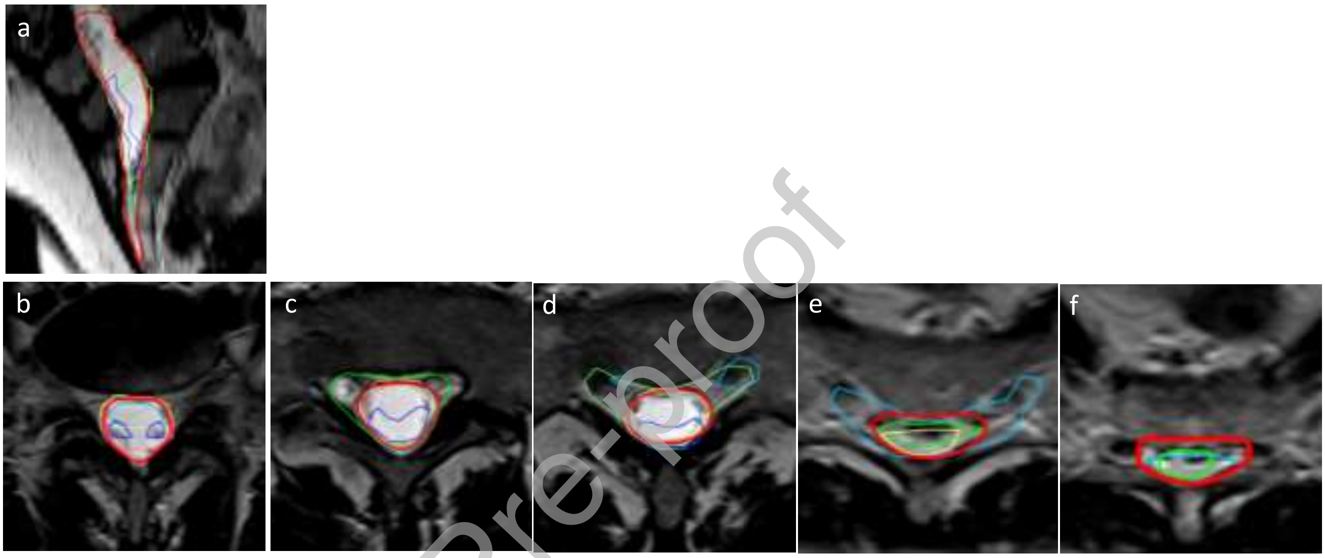
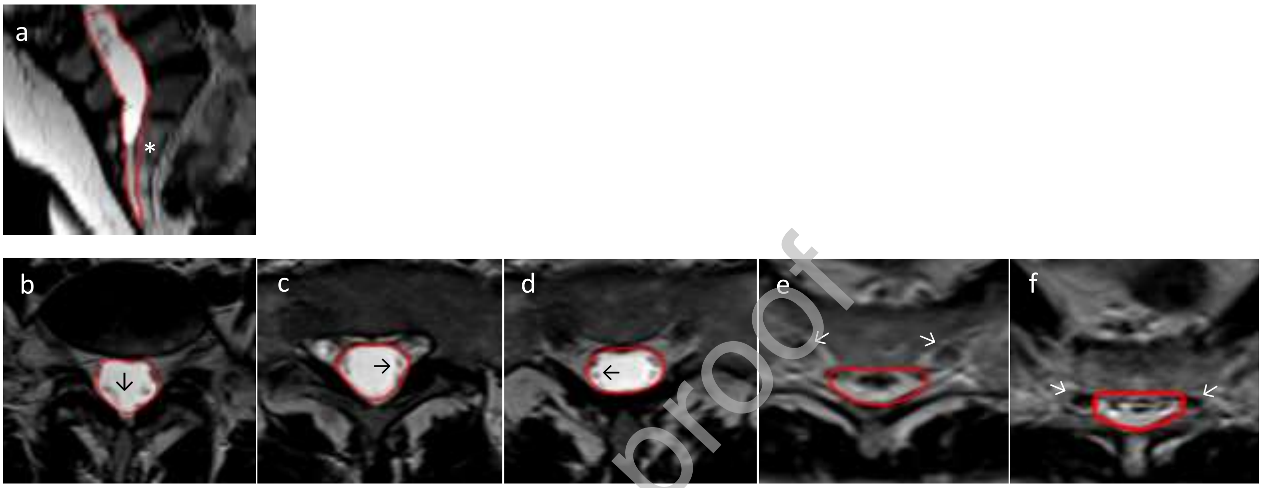


Figure 2

Selected sagittal and axial T2 MRI slices through the sacral spine with the recommended consensus contour depicted in red



The consensus contour recommends encompassing the entirety of the cauda equina and the intra-canal spinal nerves to the inferior aspect of the S5 vertebra (image a), beyond the termination of the TS (*). Axial images of the sacral spine in a craniocaudal direction are represented by images b (S1), c (S1), d (S2), e (S3) and f (S4). Black arrows (→) (images b - d) point to individual intrathecal nerves within the TS. They show up as low signal intensity on a T2 weighted MRI and are typically located in a 'U shaped' position in the posterior TS. White arrows (→) (images e - f) point to the extrathecal nerve roots outside the sacral canal merging into the sacral plexus. Caudal to the termination of the TS (images e – f), we recommend contouring the bony sacral canal up to the inferior aspect of S5. The bony canal acts as a surrogate contour of the extrathecal nerve roots that run within it.

Table 1: Critical neural structures contoured per expert and case

Case Description	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert 7	Expert 8
Case 1 **Sacral Level: S4** Lesion in VB, left of midline bulging in to the spinal canal	TS	TS + NR	TS	SC + NR	NR	SC	TS	TS
Case 2 **Sacral Level: S1** Lesion in right Ala abutting exiting right S1 nerve root	CE	TS + NR	TS	No contour submitted	NR	SC	TS	TS
Case 3 **Sacral Level: S1 – S3** Lesion in VB of S1/S2 and superior aspect S3 partially enveloping left S1 and S2 sacral foramen	NR	SC + NR	TS	SC + NR	CE + NR	SC	TS	TS
Case 4 **Sacral Level: S2/S3** Lesion in left VB and ala with extra-osseous extension into left S2/S3 neural foramen	CE	TS + NR	TS	No contour submitted	NR	SC	TS	TS
Case 5 **Sacral Level: S1-S2** Lesion in left ala, abutting the left S1/S2 neural foramen	TS	SC + NR	TS	No contour submitted	NR	SC	TS	TS
Case 6 **Sacral Level: S2** Lesion in VB at midline extending to the margin of the sacral foramen	TS	TS + NR	TS	SC + NR	CE + NR	SC	TS	TS
Case 7 **Sacral Level: S3-S3** Lesion in VB extending to right ala	CE	TS + NR	TS	SC + NR	CE + NR	SC	TS	TS
Case 8 **Sacral Level: S1** Lesion in VB, no	CE	TS + NR	TS	SC + NR	CE + NR	SC	TS	TS

extension to neural foramen.								
Case 9 **Sacral Level: S1** Lesion in VB and right ala with compression of right S1 neural foramen reaching the anterior of the right spinal canal.	TS	TS + NR	TS	SC + NR	CE + NR	SC	TS	TS
Case 10 **Sacral Level: S1-S3** Lesion in VB and left ala with extra-osseous epidural extension into the S1 and S2 foramina bilaterally.	No contour submitted	TS + NR	TS	SC + NR	CE + NR	SC	TS	TS

***Abbreviations**:* TS, thecal sac; CE, Cauda Equina; SC, sacral canal; NR, lumbosacral plexus/extrathecal nerve roots*; TS/CE/SC + NR, thecal sac/cauda equina/sacral canal and extrathecal nerve roots combined as one contour by the expert.

Explanation of nomenclature used in table:

TS: All contents within the dural envelope contoured

SC: All contents within the bony margins of the sacral canal contoured

CE: All individual intrathecal nerves within the posterior thecal sac contoured (typically a 'U' shaped contour)

*Nerve roots (NR): lumbosacral plexus/extrathecal nerves. The extent of the plexus contoured varied between individual and was dependent on the level of the sacrum being treated

Table 2: Inter observer variability metrics of Thecal Sac contour variability				
	Mean DSC	STAPLE Kappa	Mean SENS	Mean SPEC
Case 1	0.36	0.21	0.34	1.00
Case 2	0.53	0.55	0.64	1.00
Case 3	0.46	0.39	0.46	0.99
Case 4	0.42	0.28	0.41	1.00
Case 5	0.42	0.42	0.50	1.00
Case 6	0.36	0.31	0.40	1.00
Case 7	0.38	0.44	0.45	1.00
Case 8	0.44	0.44	0.46	1.00
Case 9	0.45	0.37	0.49	1.00
Case 10	0.42	0.38	0.43	1.00

Abbreviations: DSC, dice coefficient; STAPLE, simultaneous truth and performance level expectation; SENS, STAPLE sensitivity; SPEC, STAPLE specificity

Guidelines for kappa analysis (12): <0, poor agreement; 0.01–0.20, slight agreement; 0.21–0.40, fair agreement; 0.41–0.60, moderate agreement; 0.61–0.80, substantial agreement; 0.81–1.00, almost perfect agreement

Table 3: Thecal Sac Contouring Guidelines

1. The thecal sac (TS) is best identified on MRI. Fuse thin-sliced volumetric T1-weighted and T2-weighted axial non-contrast-enhanced MRI sequences to the treatment planning CT to aid delineation. In patients with titanium fixation devices in place or severe malalignment (scoliosis), a CT myelogram (performed immediately prior to CT planning) is often superior to an MRI for delineation of the TS.
2. Contour the TS encompassing all individual (intrathecal) nerves within the cauda equina.
3. Do not contour individual intrathecal nerves within the TS. Although possible to identify them using MRI, their location can be patient and position dependent.
4. We advise contouring the bony canal, caudal to the termination of the TS, up to the inferior aspect of the S5 vertebra. This ensures that the extrathecal/intracanal spinal

nerve roots that run within the bony canal are considered as an OAR and spared. The bony canal acts as a surrogate contour for the nerve roots that run within it. 5. It is good practice to contour the TS at least a level above and below the target metastases planning target volume (PTV) to avoid unintended spillage of dose to the cauda equina and nerve roots. 6. Unlike the spinal cord, no PRV is added to the TS contour for planning or application of tolerance constraints.
Abbreviations: TS, thecal sac; MRI, magnetic resonance imaging;