

***ASSESSMENT OF PROTOCOL
VIOLATIONS IN LOCAL TREATMENT
FOR RMS AND RMS-LIKE PATIENTS.***

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Polish Paediatric Solid Tumour Study Group

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Conflict of interest disclosure for SIOP 2011

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Dominika Kulej

- In number of large multicenter studies the protocol violations occur and have different influence on results.

- Aim of the report is to evaluate the impact of omitting the radiotherapy in high risk patients with RMS and RMS-like tumors registered in Polish Pediatric Solid Tumor Study Group (PPSTSG) and treated according to the protocol CWS 2002.

Patients

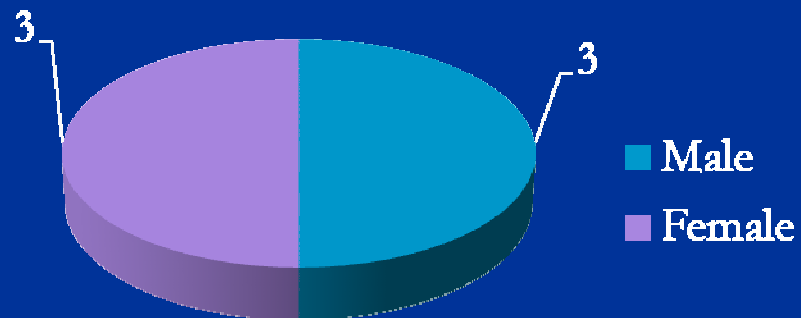
- PPSTSG (CWS 2002):
 - 181 pts with soft tissue sarcoma
 - 31 of them (aged 2-218 months and staged 1-3) were allocated to the high risk group (HRG) due to unfavourable localization or/and unfavourable histology according to CWS 2002 grouping system.
 - Follow-up: 23-93 months, M= 60 months.

Patients

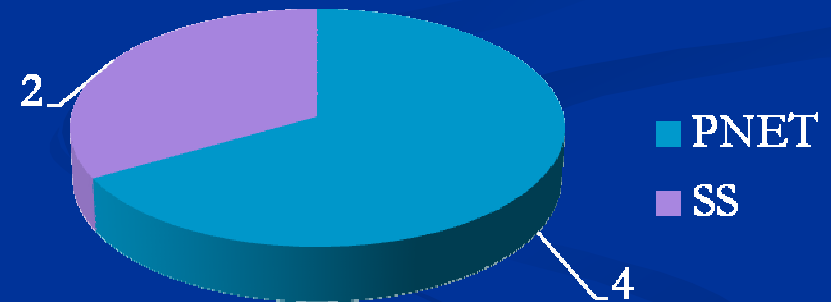
- 6/31 allocated to HRG did not received radiotherapy (XRT) despite protocol recommendation.
- 25/31 allocated to HRG due to the same reasons (unfavourable localization and unfavourable histology), received XRT according to the protocol.

Non- XRT group (6pts)

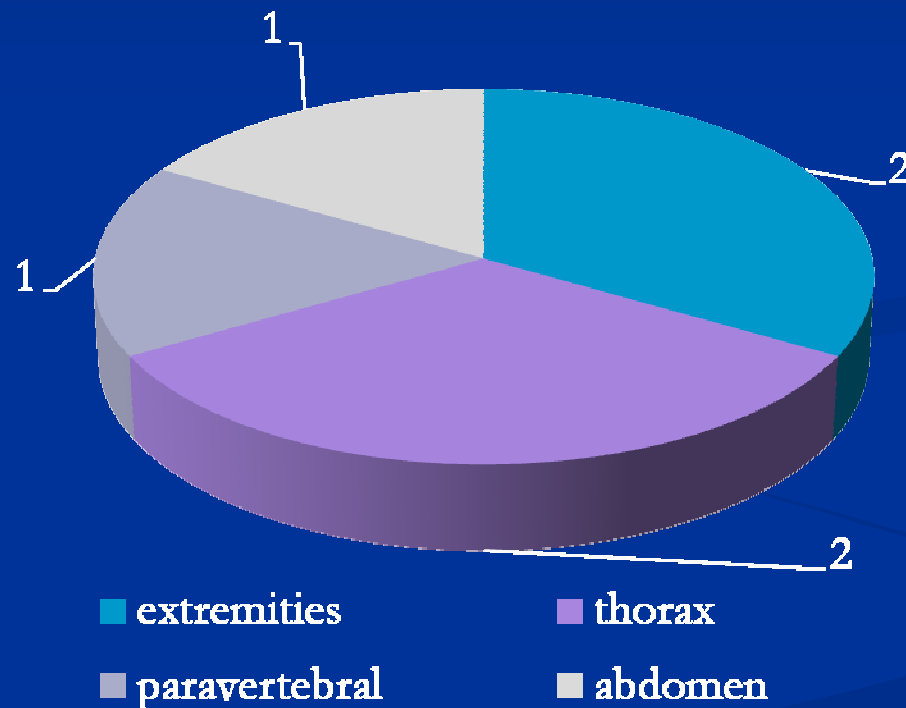
sex distribution



pathology variants



Non- XRT group (6pts) locations of primary tumours



Non - XRT group (6pts)

- primary resection:

- R0/2

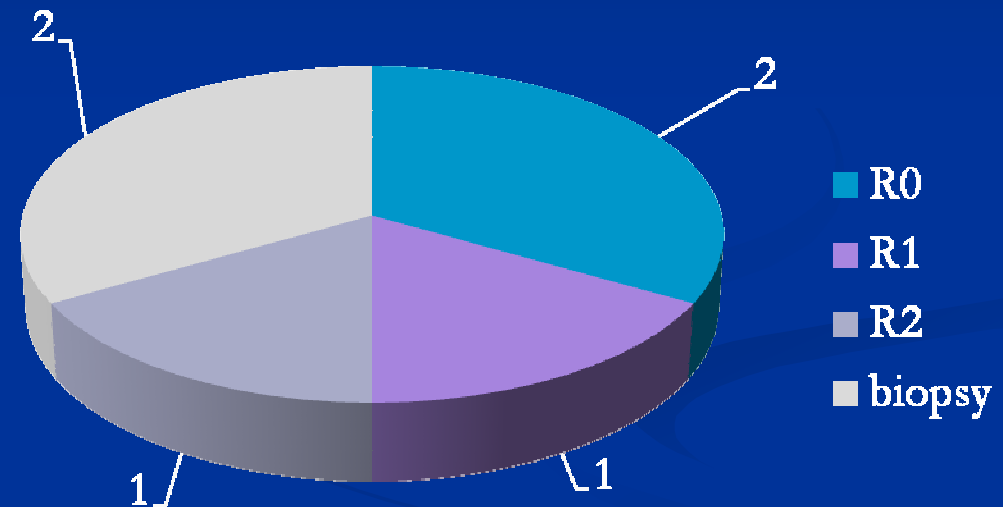
- R1/1

- R2/1

- biopsy/2

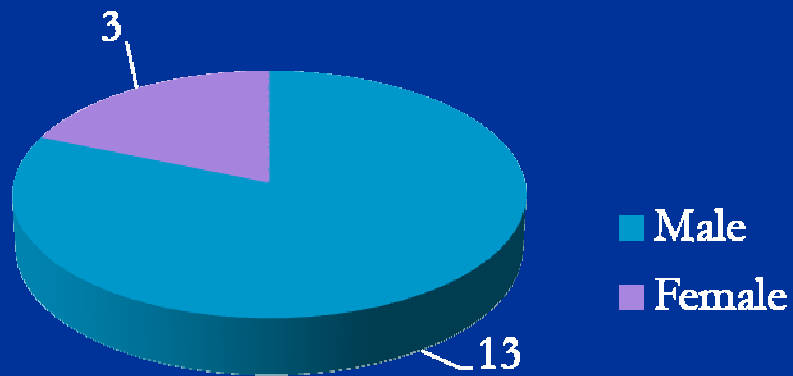
- ChT/6

- Ind surgery/1

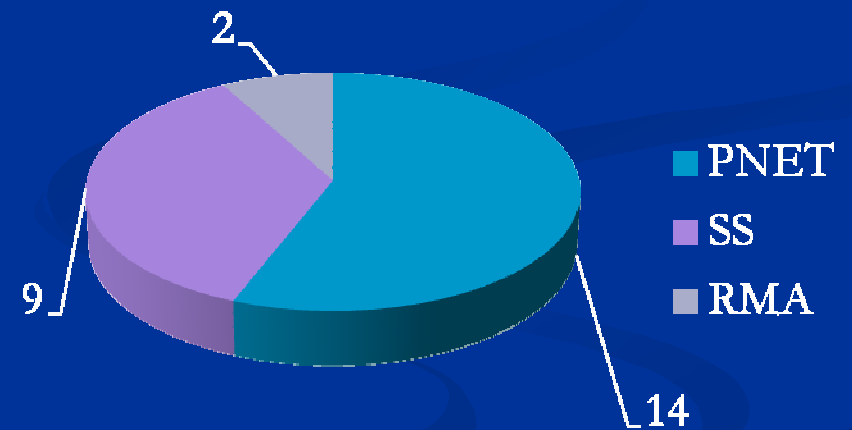


XRT group (25pts)

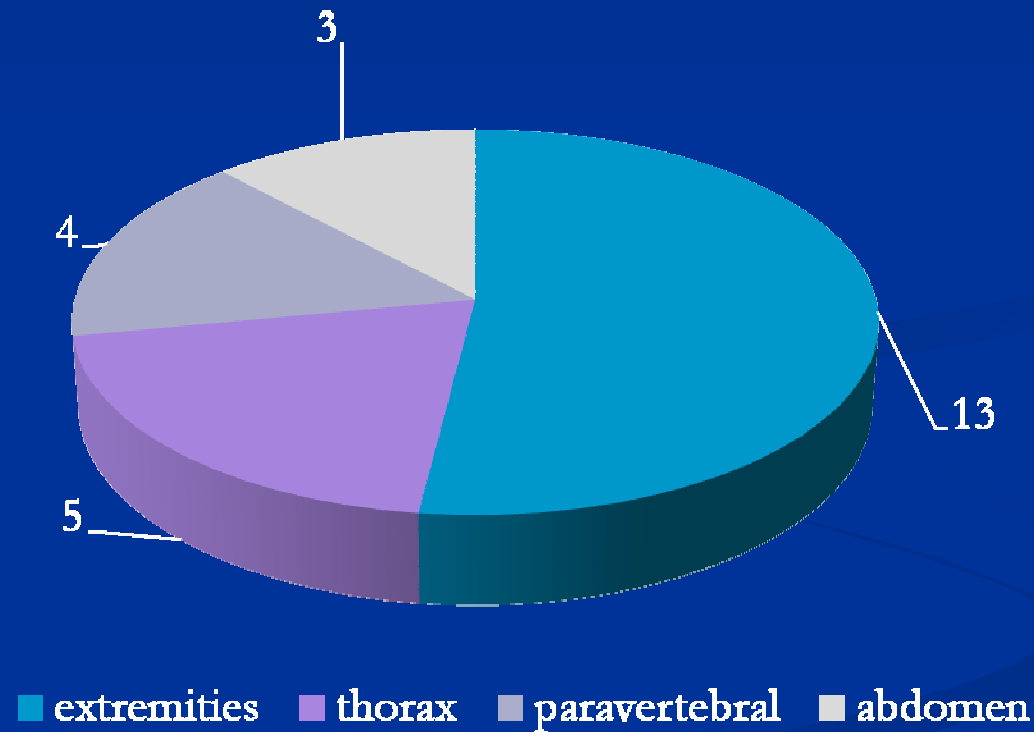
sex distribution



pathology variants

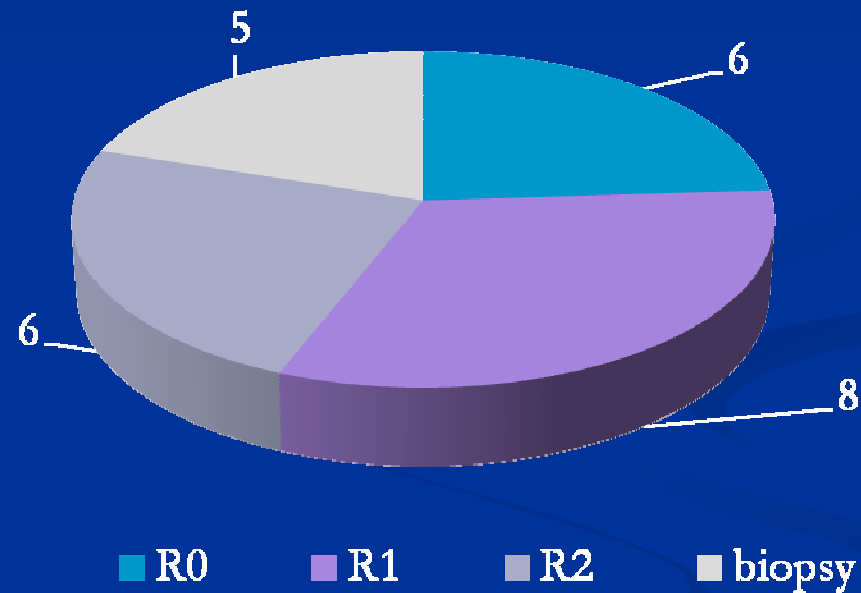


XRT group (25pts) locations of primary tumours



XRT group (25pts)

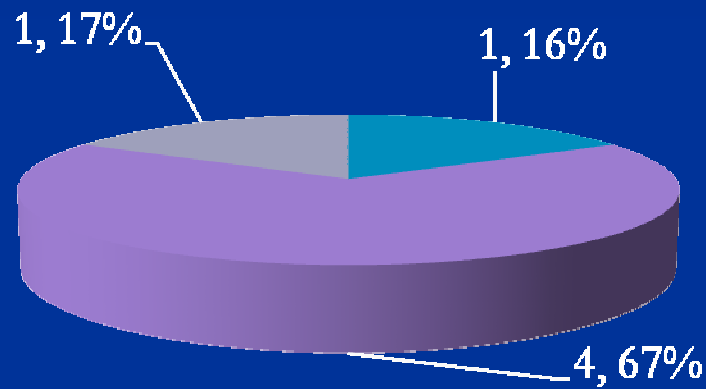
- Primary resection:
 - R0/6
 - R1/8
 - R2/6
 - biopsy/5
- ChT in all
- II surgery/2



Results

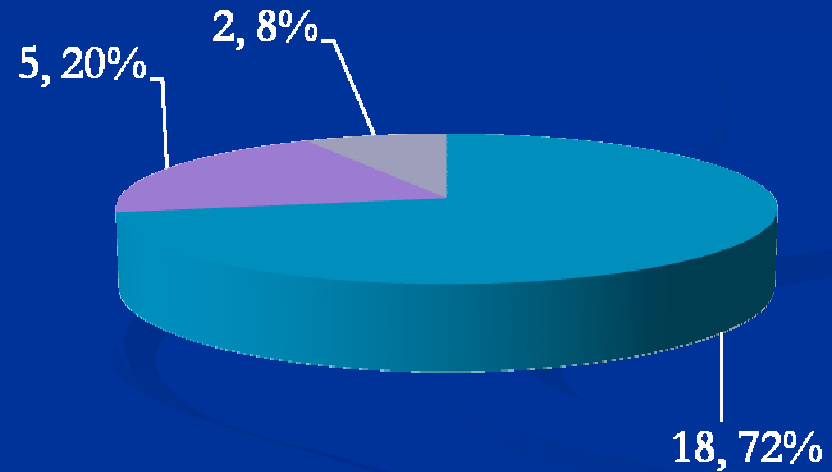
22/31 (71 %) pts allocated to HRG are alive

non-XRT group (6 pts):



- alive in 1st CR
- relapsed and died
- relapsed and achieved 2nd CR

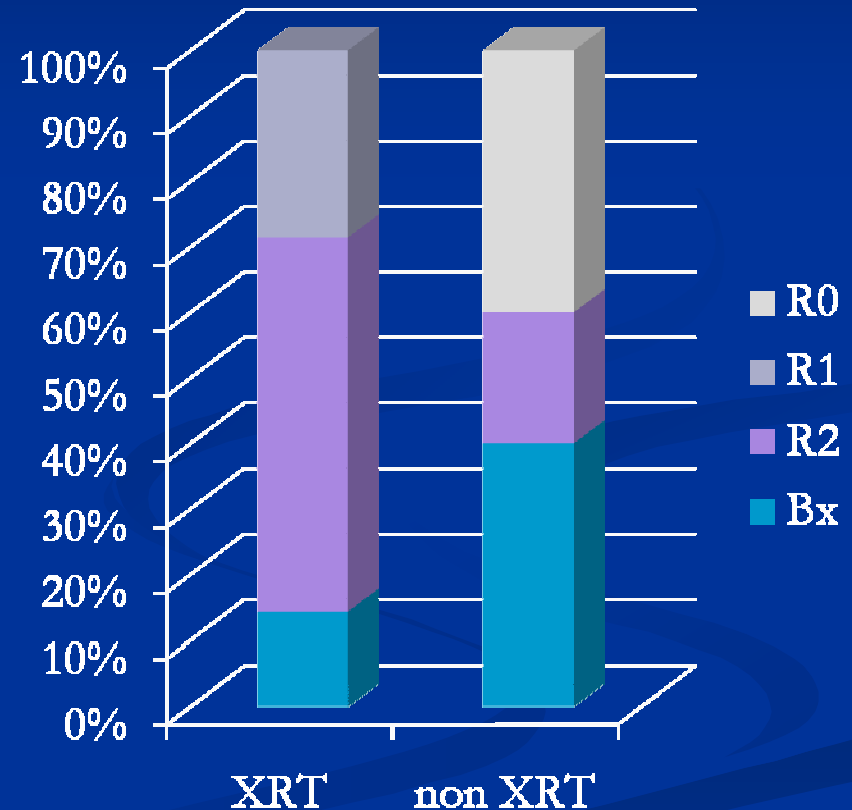
XRT group (25 pts):



- alive in 1st CR
- relapsed and died
- relapsed and achieved 2nd CR

Results

- Non-XRT pts:
 - Of 5 pts who relapsed 1 had R2, 2 biopsy only and 2 R0/2.
- XRT pts:
 - Of 7 pts who relapsed 4 had R2 resection, 1 biopsy only and 2 R1.



Conclusion

- Violation of the protocol in local treatment for high risk RMS and RMS-like tumors has negative impact on survival (5/6 vs. 7/25 relapsed)
- In these pts, local treatment with surgery alone is clearly not sufficient (also for 2 cases who had R0 resections of their tumours).

**Thank you
for your attention**