

Dr. Michelle Ghert

“The Prophylactic Antibiotic Regimens in Tumour Surgery (PARITY) Trial: Unprecedented International Collaboration in Orthopaedic Trials”

Sarcoma is rare, and the volume of individual specialized sites precludes large prospective single-centre studies. The orthopaedic oncology literature is dominated by single-centre retrospective case series, so multicentre collaboration is essential for moving the orthopaedic oncologic field forward.

Dr. Ghert envisioned a new era of research in orthopaedic oncology through large randomized controlled trials (RCTs). She was inspired by the success of her mentor, Dr. Mohit Bhandari in galvanizing the orthopaedic trauma community into conducting large multicentre RCTs. Armed with optimism, she worked towards developing a research question that could be answered by a collaboration of all orthopaedic oncology surgeons.

Bone sarcomas of the femur and tibia can be surgically excised and the limb reconstructed through “limb-salvage”. The most common method involves using endoprostheses. There is a high risk for complications, the most devastating and complicated of which is surgical site infection. This leads to multiple revision surgeries, and at least 50% of patients with an SSI end up with an amputation. A systematic review to determine the overall infection rate, and identify a baseline event rate for PARITY, was conducted, revealing a reported infection rate of 10%.

The researchers determined the practices and opinions of orthopaedic oncologists regarding prophylactic antibiotics during and immediately following these procedures. With a 75% response rate, it was determined that 33% of surgeons believed antibiotics should be discontinued after 24 hours but 40% continue antibiotics until the suction drain is removed. 90% of respondents agreed that they would change their practice if a large randomized controlled trial showed clear benefit of an antibiotic drug regimen different from what they currently use.

Dr. Ghert and her team approached colleagues across Canada and at several US centres, and formed a Steering Committee to develop the study protocol. Patients with bone tumours undergoing limb-salvage surgery and reconstruction are screened and randomized into one of two study arms: 24 hours of post-operative antibiotics or five days of postoperative antibiotics. The study is fully blinded.

The first PARITY patient was enrolled in January of 2013. Early success of the trial led to the group receiving additional funding and PARITY attracted international interest, with 21 sites across four countries in the pilot study. PARITY quickly gained international momentum and new sites opened around the world. Now, over 585 patients have been enrolled in PARITY, in 55 sites across 12 countries. PARITY is the largest international collaborative RCT in orthopaedic history in terms of the number of countries collaborating. The study will be completed in 2019 and will provide high-level evidence to direct clinical practice in the orthopaedic oncology patient population.

In answer to Dr. Ghert’s initial questions: Can orthopaedic oncologists reduce infection rates with prophylactic antibiotics? PARITY **will** answer this question. Can the international orthopaedic oncology community work together to improve sarcoma patient care? PARITY **has** answered that question.

The PARITY team has leveraged its international collaborative network for further research priorities. Optimism for success of these future endeavours is high.