RESEARCH GRANT SPOTLIGHT...

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"Intravenous cefazolin plus oral probenecid vs. oral cephalexin for the treatment of skin and soft tissue infections: a double-blind, non-inferiority, randomized controlled trial"

Co-principal investigators Dr. Dawn Dalen and Dr. Peter Zed; and co-investigators Amy Fry, Dr. Samuel G. Campbell, and Dr. Jeffrey Eppler received a Research Grant of $15,000.

Q: How did the concept/idea for your research project come about?
A: Many patients with mild to moderate skin and soft tissue infections (SSTIs) in Canada are managed using once daily intravenous cefazolin combined with oral probenecid. Although successful outcomes can be achieved with the intravenous antibiotic approach, the need for daily visits to the Emergency Department (ED) is often inconvenient for patients and incurs greater health care costs. We were interested in comparing an oral antimicrobial approach (cephalexin) to the standard intravenous outpatient regimen to determine if patients may be cared for outside of the emergency department with cure rates as good as intravenous cefazolin with oral probenecid.

Q: Briefly describe your research project and what it revealed.
A: This was a prospective, multi-centre, double-blind, randomized controlled non-inferiority trial conducted at two tertiary care teaching hospitals. Patients were included if they presented to the ED with mild-moderate SSTI and were well enough to be treated as outpatients and return to the ED daily. Our aim was to determine if cephalexin 500 mg orally four times daily was non-inferior to cefazolin 2 g intravenously daily plus probenecid 1 g orally daily for uncomplicated mild-moderate skin and soft tissue infections in patients presenting to the ED.

The primary outcome was failure of therapy at 72 hours. Clinical cure at 7 days, intravenous to oral step-down, admission to hospital and adverse events were also assessed. There were 206 patients randomized and at the 72 hour end-point 195 patients were evaluable. The proportion of patients failing therapy at 72 hours was similar between the treatment groups (4.2% and 6.1%, risk difference 1.9%, 95% CI (-3.3% to 7.1%), p-value for non-inferiority test=0.001). Clinical cure at seven days was not significantly different (100% and 97.7%, risk difference -2.3%, 95% CI (-4.9% to 0.3%), p-value for non-inferiority test=0.008). Five patients were admitted to hospital over the course of the study (4 in the cephalexin arm and 1 in the cefazolin and probenecid arm). All patients who had not been admitted or had alterations to their antibiotics were successfully stepped down to oral therapy on or before day seven. One patient experienced a rash in the cephalexin arm resulting in stopping study therapy. Cephalexin appears to be a reasonable alternative to consider in patients with mild to moderate uncomplicated SSTI who present to the ED.

Q: How will the results of your research impact hospital pharmacy and patient care?
A: The results will be used to inform patients, clinicians, researchers and policy makers on optimizing care for patients with mild-moderate SSTIs and ultimately to improve patient care and have a significant impact on the current standard of practice. If the management of SSTI is further shifted to care at home with oral antibiotics increased attention will be placed on optimal prescribing, best pharmacotherapy practice and drug therapy monitoring, and the ability to shift care to home rather than in the ED or ambulatory care setting should improve patient satisfaction and reduce disruption to their daily activities, and may help reduce the ever-growing problem of ED overcrowding and overall health care costs.

Q: What role, if any, did the research grant play in supporting your professional career?
A: This research would not have been possible without the grant. I believe I have grown as a researcher and will likely apply for other grants in the future.

Project Publication: See the CSHP Foundation **Publications** webpage.

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