EM Advances

Photodocumentation as an emergency department documentation tool in soft tissue infection: a randomized trial

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ABSTRACT

Objectives: Current documentation methods for patients with skin and soft tissue infections receiving outpatient parenteral anti-infective therapy (OPAT) include written descriptions and drawings of the infection that may inadequately communicate clinical status. We undertook a study to determine whether photodocumentation (PD) improves the duration of outpatient treatment of skin and soft tissue infections.

Methods: A single-blinded, prospective, randomized trial was conducted in the emergency departments of a community hospital and an academic tertiary centre. Participants included consecutive patients age $\geq$ 14 years presenting with noninvasive skin and soft tissue infections requiring OPAT. Patients in the intervention arm were treated with standard of care plus PD at each emergency physician assessment. Control subjects received care provided at the discretion of the treating physician and non-photographic documentation. The primary outcome was duration of therapy measured in half-days. The required sample size to detect a difference of one half-day was 253 patients per group ($\alpha = 0.05$). Secondary outcomes included (1) completion and therapeutic failure rates, (2) patient satisfaction, and (3) physician and nurse satisfaction.

Results: Enrolment was slower and follow-up rates lower than anticipated, and the trial was terminated when funds were exhausted. A total of 468 subjects with similar age and gender characteristics were enrolled, with 244 receiving the intervention and 224 in the control arm. The mean OPAT duration was similar in the two groups (3.6 days v. 3.5 days, $p = 0.73$). No differences in the rate for completion and therapeutic failure were observed (71% v. 68% and $< 1\%$ for both, respectively). Survey response rates varied significantly: patients, 65%; nurses, 17%; and physicians, 87%. Physicians endorsed more comfort with their assessment and OPAT judgment with PD (65% and 64%, respectively). Physicians cited too much time lost with technological challenges, which would affect implementation in a busy ED.

Conclusions: PD as an intervention is acceptable to patients and has reasonable endorsement by the majority of physicians. This trial had significant limitations that threatened the integrity of the study, so the results are inconclusive.

RÉSUMÉ

Objectif: Les moyens actuels de documentation des infections de la peau et des tissus mous chez les patients soumis à un traitement anti-infectieux parentéral ambulatoire (TAIPA) comprennent les descriptions écrites et les croquis des tissus infectés, mais ces moyens peuvent ne pas rendre pleinement l'état clinique. Aussi avons-nous mené une étude visant à déterminer si la photodocumentation (PD) pouvait améliorer la durée du traitement des infections de la peau et des tissus mous chez les patients externes.

Méthode: Un essai prospectif, à répartition aléatoire, et à simple insu a été mené au service des urgences d'un hôpital communautaire et d'un centre hospitalier universitaire de soins tertiaires. Ont participé à l'essai des patients consécutifs, âgés de 14 ans et plus, souffrant d'une infection non invasive de la peau et des tissus mous, qui nécessitait un TAIPA. Les sujets du groupe expérimental ont reçu des soins selon la norme, complétés par une PD à chaque évaluation faite par l'urgentologue, tandis que les sujets du groupe témoin ont reçu des soins selon le jugement du médecin traitant, complétés par une documentation non photographique. Le principal critère d'évaluation était la durée du traitement, mesurée en demi-journée. La taille de l'échantillon nécessaire pour déceler un écart d'une demi-journée était de 253 patients par groupe ($\alpha = 0.05$). Les critères d'évaluation secondaires comprenaient 1) les taux de réussite et d'échec du traitement et 2) le degré de satisfaction des patients, des médecins, et du personnel infirmier.

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Résultats: La recherche de sujets et les taux de suivi ont été inférieurs aux prévisions, et l'essai a pris fin avec l'épuisement des fonds. Au total, 468 sujets ayant à peu près les mêmes caractéristiques quant à l'âge et au sexe ont participé à l'étude: 244 d'entre eux ont été dirigés vers le groupe expérimental et 224 vers le groupe témoin. La durée moyenne du TAIPA était comparable dans les deux groupes (3.6 jours contre 3.5; $p = 0.73$). Aucun écart quant au taux d'achèvement ou d'échec du traitement n'a été relevé (71% contre 68%, et $< 1\%$ dans les deux groupes, respectivement). Par contre, les taux de réponse aux différents questionnaires ont connu des écarts très importants, soit 65% pour les patients; 17% pour le personnel infirmier, et 87% pour les médecins. D'ailleurs, les médecins ont indiqué que la PD leur avait facilité la tâche en ce qui concerne l'évaluation des lésions et la pertinence du TAIPA (65% et 64%, respectivement). Toutefois, les médecins se sont plaints d'une trop grande perte de temps en raison de difficultés techniques, ce qui pourrait compromettre la mise en œuvre de ce type de documentation dans un service d'urgence achalandé.

Conclusions: La PD comme outil d'intervention est acceptable aux yeux des patients et recueille l'appui de la majorité des médecins. Toutefois, des limites importantes sont venues entacher l'essai, mettant même en jeu son intégrité; aussi les résultats ne sont-ils pas concluants.

Keywords: hospital emergency service, intravenous injection, photography, randomized controlled trial, soft tissue infections

Outpatient parenteral anti-infective therapy (OPAT) has emerged as an effective, safe, and cost-effective treatment option for skin and soft tissue infections (SSTIs).[1–3] The increasing use of OPAT prompted the first Infectious Diseases Society of America (IDSA) practice guideline for community-based parenteral anti-infective therapy in 1997, which was recently updated in 2004.[4,5]

We found no clinical data on the validity or reliability of documenting response to therapy despite many recent published reviews on the topic of SSTIs.[6–11] There is a paucity of data to guide physicians on when to switch to oral therapy,[12] and the only available guidelines are based on expert opinion from the Clinical Resource Efficiency Support Team (CREST) in 2005.[13] These guidelines suggest switching to oral therapy under the following conditions: diminishing pyrexia, less intense erythema, falling inflammatory markers, and stable comorbidities. These criteria can be difficult for emergency physicians (EPs) seeing patients for the first time to judge.

Several studies have incorporated the use of serial photography for chronic skin lesions such as foot ulcers, dysplastic nevi, and arterial ulcers.[14–17] However, to our knowledge, no study has been done incorporating this tool in OPAT programs for SSTIs, nor has digital photography been formally studied in an emergency department (ED) setting.

Some authors have suggested that the duration of OPAT should be 3 to 4 days and that longer therapy does not correlate with improved outcomes.[12,18–20] Knowledge of when to stop OPAT, however, requires some clinical end point. Among SSTI interventional studies, there is no consistent definition but rather a range of end points from complete resolution of symptoms to stabilization or regression of the size of erythema.[21–23]

We hypothesized that photodocumentation (PD) may assist in physician decision making, allowing earlier step-down to oral therapy. This in turn could lead to fewer ED visits, improved patient flow, and decreased costs. Our hypothesis is grounded in the belief that most EPs, in the absence of clear evidence of improvement, will tend to continue OPAT rather than step down to oral therapy. Photographs may provide earlier objective evidence of infection regression, signaling an appropriate time to discontinue OPAT. Conversely, if the photographs were to show no change in the appearance of an area of cellulitis, a physician who may have otherwise discontinued OPAT on the basis of duration of therapy already given or the patient's subjective impression of improvement may, as a result, continue OPAT.

Our objective was to compare the duration of OPAT for SSTIs in ED patients treated with digital PD and standard care compared to standard care alone. Secondary outcomes of interest addressed OPAT completion rates and failure rates after conversion to oral therapy, physician and nurse perceptions of quality of care, documentation and workload, and patient satisfaction.

METHODS

Design and eligibility

This prospective, randomized, single-blinded trial enrolled consecutive patients age $\geq$ 14 years presenting

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to the ED with nonnecrotizing SSTIs requiring OPAT. Patients were excluded if they presented with necrotizing or invasive infections or non–soft tissue infections (e.g., pneumonia, pyelonephritis, osteomyelitis), were under age 14, were previously enrolled in the trial, were unable to consent, or were admitted to hospital. Ethical approval was granted by the institutional research ethics boards of both participating hospitals (one academic, one community).

Intervention

Determination of eligibility and enrolment was done by either the treating physician or the nurse. Missed cases were identified through chart review and subsequently enrolled. Subjects randomized to the PD arm had one to three photographs taken of their infected site initially and at subsequent EP assessments. Photographs were taken by the attending physician or nurse after having received basic training on the use of the camera equipment and previously published photographic technique.[17] Instructions for camera operation and photographic technique were printed on a laminated card easily accessible to staff. A "point and shoot camera" was selected with settings on automatic to maximize the simplicity of the PD procedure. Clinicians were encouraged to take a wide (zoomed out) shot to provide perspective and one or two closer shots, with the area of interest filling the frame. Photograph rulers were available for inclusion in the shots to provide a measurement scale at the discretion of the clinicians.

Control arm

Subjects allocated to the control group received current standard of care documentation without the use of photography, which may have included drawings in the chart and/or skin markings with a surgical ink pen. The level of care provided to the control group was not monitored in terms of compliance with current guidelines and varied at the discretion of the treating physician.

Randomization

The study assignments were randomized through an online random number generator in permuted blocks of 10 and distributed in concealed envelopes. Once enrolled, the enrolling nurse, EP, or research assistant handed the subject the next study pack from the pile, with group allocation being revealed on opening the envelope.

Blinding

After randomization and opening of the envelopes, the assignment was nonblinded except for statistical work.

Outcomes

The primary outcome measure was duration of OPAT in days. The secondary outcome measures were (1) therapeutic failures, defined as reinstitution of OPAT within 7 days of stepping down to oral therapy; (2) patient satisfaction with care, and (3) physician and nurse satisfaction with the PD protocol.

Statistical methods

Our primary outcome was analyzed using the independent samples *t*-test. Quantitative secondary outcomes were compared using chi-square testing, and Mann-Whitney *U* testing was performed for survey data.

Sample size

Sample size calculation was based on a mean number of treated days of 3.5 with standard care (twice-daily intravenous [IV] therapy) and an estimated standard deviation of 2 days of OPAT, with a clinically meaningful end point defined as a 0.5-day reduction in the mean number of treated days, which translates into a reduction in at least one ED visit per day to receive IV therapy. We chose this as a relevant end point because it is the smallest measurable time interval in this setting and would still likely be meaningful to the patient, who would save a visit to the ED, with the associated wait and IV therapy in situ. We calculated a sample size of 253 subjects per group with 80% power and a two-sided α of 0.05 to detect a 0.5-day reduction in the mean number of treated days.

Data collection

All quantitative data were abstracted by staff independent from the clinical relationship but not blinded to the intervention. All subjects in both arms of the trial received six- and seven-item satisfaction questionnaires

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at their initial assessment (at institution of OPAT) and at the final assessment (discharge from OPAT and/or transition to oral step-down therapy), respectively. These were administered either by the nurse taking care of the patient or the research assistant.

At the end of the trial period, questionnaires were administered to all EPs and nurses staffing both departments. The survey was designed to assess any perceived change in the EPs' confidence in judging clinical progress, as well as EP and nurse overall satisfaction with the feasibility of the protocol.[24] Questionnaires were created according to published guidelines[25] and reviewed by three experienced clinician-researchers. Questionnaires were drafted using an online software tool (<http://www.surveymonkey.com>) and sent electronically to all EPs and nurses.

RESULTS

Quantitative data

The study was terminated before reaching the planned sample size due to slower than anticipated enrolment and higher loss to follow-up, which exhausted available funding. Of 500 patients initially enrolled, 5 were protocol violations as they were under 14 years of age and 27 were lost to follow-up (5%), leaving 468 patients (93% of the planned sample) in the final analysis. Of these, 244 were in the photography arm and 224 in the control arm.

Recruitment occurred from October 2009 through December 2010. Baseline subject data are shown in Table 1. The mean OPAT duration was 3.6 days in the intervention group and 3.5 days in the control group ($p = 0.73$; Table 2). In addition, the completion rate of OPAT from the ED (as opposed to referral to an infectious diseases (ID) clinic) was similar between the two groups, with values of 71% and 68% ($p = 0.54$), respectively; therapeutic failure rates were similar as well (0.8% PD and 0.9% control, $p = 0.93$) (see Table 2).

Table 1. Baseline subject demographics in the photodocumentation and control arms

	PD	Control
Number of subjects	244	224
Age (yr)		
Mean (SD)	49.9 (17.0)	49.2 (14.4)
Range	15–95	14–89
Percent male	60	62

PD = photodocumentation.

Patient survey results

The patient rate of completion of the entrance survey was 87% and for the exit survey was 65%. Table 3 and Table 4 document minimal categorical significance in the responses, with a median of 4 = agree or 5 = strongly agree across all questions, with the exception of neutral agreement among patients in both arms that they would prefer more attention be given to the status of their infection.

Physician survey results

Twenty-seven of the 31 eligible EPs responded to the online survey (87%) (Figure 1). Physician responses to the PD protocol were predominantly positive. Only 25% of those surveyed believed that the current standard of care represents adequate documentation and assessment of these patients. Sixty-five percent felt more comfortable with their assessment of the patient when a photograph accompanied the chart, and 64% reported improved confidence in their judgment to continue or stop OPAT. Roughly three-quarters of EPs felt that pictures represent superior documentation. Nineteen percent of participating EPs reported that the PD protocol did not improve either assessment or confidence in decision making. When asked whether PD should be implemented routinely hereafter, 33% favoured implementation in all patients and 81% favoured it in selected patients; however, the sample size was insufficient to explore these subgroups.

The majority of physicians had reservations on feasibility, citing additional time taken to implement the protocol in a busy ED, inconsistency of photographer technique, and limited added value.

Table 2. OPAT duration, completion rate, and treatment failure rate in the photodocumentation and control arms

	PD	Control	*p*
Mean OPAT duration in days (SD)	3.6 (2.4)	3.5 (2.3)	0.73*
Completion rate	71%	68%	0.54†
Treatment failure	0.8%	0.9%	0.93‡

OPAT = outpatient parenteral anti-infective therapy; PD = photodocumentation.
*Two-tailed *t*-test [$t(466) = 0.34$, $p = 0.73$].
†Chi-square test [$\chi^2(1, N = 468) = 0.37$, $p = 0.54$].
‡Chi-square test [$\chi^2(1, N = 468) = 0.007$, $p = 0.93$].

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Table 3. Subject survey results at initiation of OPAT expressed as median values*

Survey question	PD	Control	*z* score†	*p*
1. I am satisfied with the care I am receiving for my skin or soft tissue infection.	4	4	−0.958	0.34
2. I would prefer more attention be given to the status of my infection.	3	3	−1.785	0.07
3. I feel the current status of my infected site was adequately assessed.	4	4	−1.757	0.08
4. I feel the current status of my infected site can be adequately documented in the chart.	4	4	−1.471	0.14
5. I am confident that the next physician who sees me will be able to determine if my infection is getting better or worse or is unchanged.	4	4	−1.108	0.27
6. I am comfortable with the concept of a photo being used in a medical chart to document a soft tissue infection.	5	5	−0.536	0.60

OPAT = outpatient parenteral anti-infective therapy; PD = photodocumentation.
*1 = strongly disagree, 2 = disagree, 3 = neutral/unsure, 4 = agree, 5 = strongly agree.
†Mann-Whitney *U* test of mean ranks between the two study arms.

Nurse survey results

Only 40 of the 242 nurses who were sent the registered nurse survey responded (16.5%). Unfortunately, due to the large pool of casual and part-time nursing staff and the inability to track which nurses treated eligible patients, we were obliged to send the survey to the entire group rather than select only for those involved in the trial. Seventy percent of responding nurses agreed that the protocol was logistically feasible, 75% believed that PD did not increase wait times in the ED, and 92% supported routine implementation.

DISCUSSION

PD did not significantly reduce the duration of parenteral outpatient therapy for patients with SSTIs in a trial that was stopped prematurely secondary to cost overruns. Patients, physicians, and nurses perceived PD to be helpful when compared to the current standard of written documentation; however, physicians were less likely to endorse it, citing reservations with technological challenges (photograph inconsistency), increased time to use, and limited value added.

There are protocol-related issues that can be edifying for those who wish to pursue future evaluations of this treatment adjunct. First, the PD protocol itself encountered difficulties that may have reduced the effectiveness of the images. Although a training session was given to ED staff prior to the study and an instructional sheet accompanied the workstation, there was nonetheless significant variability in lighting, framing, and staging, resulting in inconsistent colour temperature and use of a flash. These factors contributed to making direct photograph-to-photograph comparison at times challenging. A solution to this might be to create consistent conditions for ED photography, such as an external light source, appropriate draping to minimize distracting background or light reflection, and a ruler to provide scale. Although criteria for grading image quality were not defined, higher quality images yielded a positive endorsement from participating EPs.

Table 4. Subject survey results at discharge of OPAT expressed as median values*

Survey question	PD	Control	*z* score*	*p*
1. I am satisfied with the care I am receiving for my skin or soft tissue infection.	5	4	−2.461	0.01
2. I feel there was adequate continuity of care from my last visit(s) to the current one.	5	4	−2.164	0.03
3. I feel the doctor was accurately able to assess the progress of my infected site.	5	4	−2.472	0.01
4. I have no problem with the fact that I am seen by different doctors and nurses at each visit.	4	4	−2.685	0.007
5. Given the option, I would prefer digital photographs be taken of my infected site.	5	4	−5.482	0.000
6. I am comfortable with the idea of having photographs added to my chart to document my progress.	5	4	−4.910	0.000
7. Digital photography is a superior method of tracking my infected site.	5	4	−3.401	0.001

OPAT = outpatient parenteral anti-infective therapy; PD = photodocumentation.
*1 = strongly disagree, 2 = disagree, 3 = neutral/unsure, 4 = agree, 5 = strongly agree.
†Mann-Whitney *U* test of mean ranks between the two study arms.

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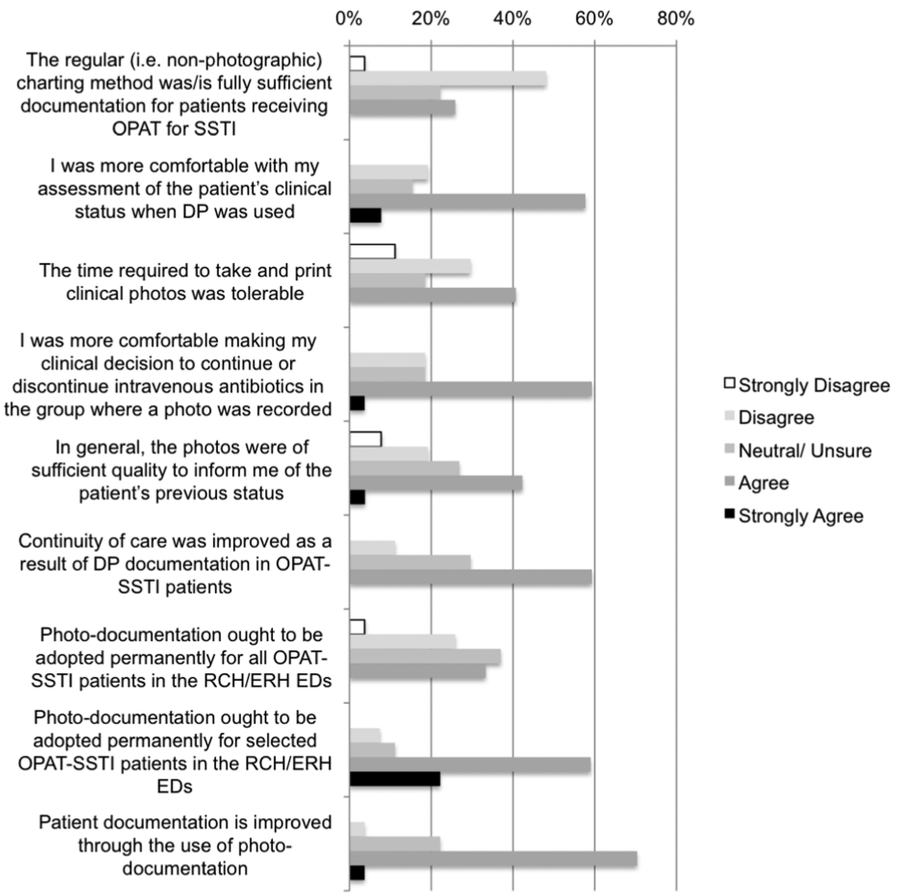

Figure 1. Emergency physician survey responses (n = 27). DP = digital photography; ED = emergency department; ERH = Eagle Ridge Hospital; OPAT = outpatient parenteral anti-infective therapy; PD = photodocumentation; RCH = Royal Columbian Hospital; SSTI = skin and soft tissue infection.

Although the workload was reportedly a concern with the EPs, the time burden of such a protocol can be mitigated by streamlining the processes of photography (e.g., clear delegation of responsibility, easy access to equipment) and appending photographs to the chart (e.g., either hard copies or digital images in an electronic medical record).

Given these challenges in implementation, it may be that PD simply does not add value to the current practice of assessment and judgment of SSTIs. It is possible that the current practice of outlining the extent of erythematous spread, in combination with the patient's own perception of improvement or worsening, is all that is needed to guide the physician in the continued use of OPAT.

Patients did endorse PD and stated that photographic images, in the setting of outpatient reassessments by different physicians daily, were perceived to be a useful adjunct that may have improved continuity of care. Patients were very comfortable with the idea of having photographs taken and added to their medical chart. Interestingly, however, subjects in the control group generally felt well taken care of (median score 4 or "agree") in terms of satisfaction with care, perceived accuracy of documentation, and continuity from one visit to the next. Even so, they also stated that they would have preferred to have had photographs taken. Photographed patients reported greater satisfaction in all of the above categories, with a median score 1 point higher than that of their counterparts.

Limitations

We acknowledge several limitations to this study. First, our recruitment fell short of the targeted 506 subjects. Recruitment was a challenge due to time constraints. Although it was intended that consecutive patients would be enrolled, the reality was that some patients were missed (number not known). This introduced potential for sampling bias into our study. Reasons for not enrolling certain patients related mostly to ED flow and volume but may also have included factors such as perceived willingness to give consent, region of the body affected, availability of the camera equipment,

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and personal biases for or against the study. To maintain an adequate rate of recruitment, small prizes were offered as incentives to top enrollers, thus introducing some recruitment bias as well.

Due to limited time and resources, valuable covariate data pertaining to the premorbid medical complexity of patients (e.g., diabetes, immunosuppression, resistant organism) were not collected, which meant that it was not possible to perform an adjusted analysis to explore potential associated benefits with subgroups of SSTI patients. Additionally, the lack of a standardized protocol for the duration of parenteral therapy prior to switching to oral therapy may have confounded our results in an unpredictable way as it was left to physician discretion to determine the current standard of care. Compliance with current guidelines was not measured in either arm, so there are no assurances that the standard of care was uniformly applied in all eligible and enrolled cases.

Unfortunately, the protocol had to be changed after the 240th subject was enrolled during an interim planned review of the data and methods (no statistical analyses done). When the protocol was initially developed, our institutional practice was that EPs reassessed OPAT patients every 24 to 48 hours, thus allowing for 1 to 2 days between each set of photographs. After initiation of the trial, however, administrative requirements changed the practice such that EPs were to reassess patients on each visit (once or twice daily). Hence, photographs with each EP assessment meant doing them at least once a day, which resulted in (1) minimal change from one photograph to the next and (2) staff resistance to the unnecessarily labour-intensive protocol. From this time to the end of the study, EPs were encouraged to repeat photographs every 2 days, or more often at their own discretion, depending on whether a noticeable change was present. The timing of the imaging was inconsistent across this subgroup of patients.

By design, physicians, nurses, and patients became unblinded to treatment group allocation. This opened the door to bias on the part of the treating physician and nurse, who may have altered their management based on knowledge of group allocation or preconceived ideas of the value of photography rather than solely on the presence or absence of photographs. Similarly, patients in the intervention arm knew they were in a trial assessing the impact of PD and may have altered their perceptions as a result of that knowledge. However, the finding that differences in satisfaction existed only on the exit survey and not on the initial survey (see Table 3) would argue against a major patient bias in this regard.

Finally, 30% of patients in either group did not complete OPAT in the ED (i.e., step-down to oral therapy). This represents a large subset of patients for whom ultimate outcome data are missing. Most of these patients (66% and 76% in the PD and control groups, respectively; data not shown) were referred to and thereafter followed by ID clinics. The remainder may have been noncompliant with therapy and lost to follow-up, whereas others may have finished their care at another institution or physician's office.

Based on these data with the limitations discussed above, the results do not support a change in current practice.

Future directions

Further studies should address the limitations of this feasibility study prior to implementation. A more rigorous scientific design with agreement from the treating physicians to implement a standardized treatment protocol in a uniform way would provide a definitive answer on whether this intervention is feasible and effective. Securing adequate funding to recruit to the required sample size and optimize follow-up may identify subgroups in which a clearer benefit to PD can be demonstrated, for example, complicated subsets of SSTIs such as those refractory to first-line treatment or involving patients with premorbid conditions complicating their course of disease. This study intervention, if proven to be superior or at least equivalent to the current standard, has the potential to be helpful in remote regions where physician access is limited, in patients with reduced mobility who cannot easily commute to a clinic, or in home outreach OPAT programs run by nurses or via IV pumps.

CONCLUSIONS

We found that implementation of this randomized controlled trial revealed significant limitations in the design, evolution of care, and challenges in recruitment and follow-up. We were unable to demonstrate that implementation of a PD protocol in addition to standard care for patients receiving OPAT for SSTIs was superior to standard care alone for the duration of therapy. PD was perceived by the patients, EPs,

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and nurses to be helpful. The protocol implementation was limited by funding resources and did not achieve the required sample size, had loss to follow-up of greater than 1%, and lacked a standardized clinical approach to the OPAT population across all physicians for the control and the treatment arms. Future studies to compare PD of SSTIs should address the shortcomings outlined in this article prior to implementation.

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