The added value of routine radiographs in wrist and ankle fractures

Gerven, P. van

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General discussion and future perspectives

Worldwide, healthcare expenditures are rising rapidly. To combat this growing problem, physicians are challenged to reduce costs while delivering high-quality healthcare. One of the ways to achieve this is to reduce the so-called 'low-value care'. In 2012, the 'Choosing Wisely' campaign was introduced to combat this problem.[1] Choosing Wisely aims towards choice of care that is 'necessary, relatively safe, and supported by evidence'. Routine radiography for distal radius fractures and ankle fractures without a clear indication or without impact on fracture treatment or patient reported outcomes is a good example of potentially low-value care. In that vein, the generally accepted principle of routine radiographic follow-up for those with distal radius fractures and ankle fractures would appear to warrant further examination, particularly given their common occurrence.

While distal radius fractures and ankle fractures have been studied extensively, most of those efforts focused on recovery following surgery, to the detriment of other areas where knowledge is lacking, such as the use and added value of routine radiography in the follow-up of extremity fractures. Prior to conducting the Warrior Trial, we employed a broad search strategy in order to identify what was known on the use of routine follow-up radiography in those with upper or lower extremity fractures. To our dismay, we found that not much was known. At that time (October 2018), we identified only eleven studies, all of them retrospective.[2-12] We were, therefore, not able to answer our research questions validly, which is summarized in Chapter 2.

In short, eight studies reported modifying their treatment strategy based upon the radiographs (percentages of modifications ranging from 0% to 2.6%). Just two of these studies used a comparative design. All the studies concluded that routine follow-up radiographs do not have important clinical consequences. This is in accordance with routine radiography for other conditions, such as knee osteoarthritis or low-back pain.[13, 14] The level of evidence was low, therefore, the results should be interpreted with caution.

CURRENT PRACTICE

In the current treatment and follow-up protocols, patients with a fractured ankle or distal radius are treated with either operative fixation or plaster immobilization. Patients receive follow-up with frequent monitoring in the outpatient clinic. Routine radiographs are performed in order to monitor fracture healing. A detailed report which describes how four level-1 trauma centers in the Netherlands organized follow-up for these patients, and how often routine radiographs are utilized during this follow-up is outlined in Chapter 3. For the purpose of that study, we focused on follow-up after the initial three weeks of treatment because these protocols are more standardized. In short, the vast majority (98.8%) of routine radiographs after three weeks of follow-up did not lead to a change in treatment strategy, but led to an increase in cost, effort and radiation exposure.

A standardized follow-up regimen, with routine radiographs obtained at fixed moments certainly can have benefits. Having a uniform follow-up protocol can aid less experienced physicians in delivering a constant level of care. Also, radiographs might protect physicians against litigation claims. This is not a common problem in the Netherlands but may be an important driver in other parts of the world, where physicians are at greater risk for malpractice litigation. However, given the large differences in both patient-specific and fracture-specific criteria, a standardized, one-size-fits-all approach seems outdated.

The most important limitation to the study outlined in Chapter 3 was its retrospective design. This limited the validity of our results. In order to provide a higher level of evidence, a prospective trial was needed. The Warrior trial was designed to evaluate whether a reduction in routine radiography for patients with a distal radius fracture or ankle fracture is effective, safe and cost-effective compared with usual care.

THE WARRIOR TRIAL

The Warrior trial was designed as a prospective, randomized controlled trial (RCT) with a four-armed design comparing reduced imaging with usual care for both ankle fractures and distal radius fractures. The inclusion criteria of the study were broad, and we had few exclusion criteria. Therefore, the external validity of the results can be considered appropriate for Western societies. The primary outcome measure was functional outcome,[15] and we opted for a non-inferiority design because we hypothesized that reducing the number of routine radiographs would be beneficial, but need not be more effective. By choosing a non-inferiority design, it was possible to prove that reducing the number of radiographs was not worse than standard care. If reduced imaging is non-inferior for function outcome, other benefits (such as lower cost, fewer side-effects or less burden for patients or the healthcare system) might then favor the implementation of reduced imaging.

Methods

Functional outcome was measured by the Olerud-Molander Ankle Score (OMAS) for those with ankle fractures,[16] while the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire[17] was used to measure functional outcome in patients with distal radius fractures. Secondary outcomes included functional outcome measured with the American Academy of Orthopaedic Surgeons (AAOS) foot and ankle questionnaire for ankle fracture patients,[18] functional outcome measured with the Patient-Rated Wrist/Hand Evaluation for distal radius fracture patients,[19, 20] Health Related Quality of Life (HRQoL), pain, self-perceived recovery, complications and costs. Participating hospitals[†] were representative of usual care.

Results

The results suggest that reduced imaging does not lead to worse outcomes in those with ankle and distal radius fractures as compared to usual care. Other outcome parameters such as AAOS scores, HRQoL, pain, and self-perceived recovery did not differ between groups either and complication rates were similar. For both ankle fractures and distal radius fractures, participants which were randomized to reduced imaging received a median of 1 radiograph less compared to those who received usual care. Clinical and functional outcomes for ankle fracture patients are reported in more detail in Chapter 4 and outcomes for patients with a distal radius fracture are reported in detail in Chapter 6.

Limitations

There are several limitations, but perhaps the most important one is the choice of the primary outcome measure. In retrospect, it could have been more appropriate to focus on the number and type of complications. It could be argued that reducing the number of routine radiographs might result in a delayed detection of a complication or fail to detect it altogether. This could be an important reason to continue routine radiographic monitoring in those with extremity fractures. This is especially so, if a missed complication could result in irreversible harm, or result in high medical malpractice compensations. A small cost saving per patient for an enormous group could be nullified by a single malpractice claim, particularly in countries where medical litigation is more common than in the Netherlands. However, it is important to realize that the current timing of follow-up radiographs is empirical with no scientific basis for detecting complications.

Since our study focused on the functional outcome of an entire group, a single or a small number of outliers with a missed complication are not likely to result in worse outcomes. A study which focused on complications as its primary outcome measure would provide the best evidence, however, such a design is not feasible because it would require a very large sample size. Typical complications that could be diagnosed on radiographic

[†] Leiden University Medical Center (LUMC), University medical Center Groningen (UMCG), Amsterdam University Medical Centers (A-UMC), Haaglanden Medical Center (HMC), ZiekenhuisGroep Twente (ZGT), Zaans Medical Center (ZMC), Flevoziekenhuis Almere.

imaging in our study were non-union, malunion, failing of the osteosynthesis and secondary dislocation. We recorded 13 of these complications in 246 patients with an ankle fracture (5.3%) and 14 in 326 patients with a distal radius fracture (4.3%) with an equal distribution between usual care (15/294 = 5.1%) and reduced imaging groups (12/278 = 4.3%). Powering a study on an outcome that is this rare and consequently will not lead to a large difference between groups, would have resulted in thousands of participants per group. Obviously, that is not a realistic option within the frame of a RCT.

When analyzing our results, the equal distribution of radiographic complications suggests that no complications were missed in the reduced-imaging group. But since the study was not powered to detect such a difference, these results should be interpreted with caution. A possible explanation why reducing the number of routine radiographs did not lead to missed complications might be that patients with a non-union, malunion or a secondary dislocation, typically exhibit other symptoms, such as pain or diminished range-of-motion. Since these symptoms were indications to obtain radiographs in the reduced-imaging group, we may have missed patients with asymptomatic complications. One might argue whether this has clinical consequences. If a patient, for instance, has a slight malunion, but is not exhibiting any symptoms, it is questionable whether it is necessary or desirable to correct this malunion.

A second limitation regards the subgroup analyses, which we performed for operatively treated and non-operatively treated patients. The percentage of patients that received operative treatment of a distal radius fracture was lower (12.6%) than we had estimated based upon our retrospective study (20%). Our results suggest no worse outcomes for the reduced imaging strategy, although this should be interpreted with caution because this analysis was underpowered. However, the chance that a routine radiograph of an asymptomatic patient leads to detection of a complication which is likely to influence treatment strategy is thought to be negligible. Therefore, routine radiography would appear not necessary for those with an operative fixation of their distal radius fracture. Another subgroup analyses that might have been interesting to explore include comparing outcomes for patients with an unstable fracture managed non-operatively. This was not conducted because there were insufficient numbers as we did not power for this subgroup.

A third limitation is the number of protocol violations. For patients in the usual care group, it was obligatory to obtain a radiograph both at 6 and 12 weeks of follow-up. We witnessed that, mainly in patients with a distal radius fracture, not all patients randomized to usual care received both follow-up radiographs. Out of 166 patients with a distal radius fracture randomized to usual care, just 97 (58%) had a radiograph both at week 6 and 12. This might indicate that the current follow-up protocol for distal radius fractures is overly cautious and that in regular clinical practice clinicians may already carefully consider whether an additional radiograph is needed or not. On the other hand, this might also be a result of the information we provided to participating clinicians about the research question and study design. This may have created more awareness about the usefulness of routine radiographs during follow-up.

In contrast, in those with an ankle fracture, protocol violations were predominantly observed in the reduced imaging group. The protocol violations in this group usually occurred if a radiograph was made at week 6 or 12 when the clinical indication was not present or registered. Out of 118 ankle fracture patients randomized to reduced imaging, 59 had a protocol violation (50%). This high number might be, however, an indication that the reason for radiographs was not accurately reported. It might also indicate that physicians regarded the number of radiographs in the reduced imaging protocol for ankle fractures as insufficient. Despite this, we do not believe that these protocol violations introduced bias. We performed a per-protocol analysis for ankle fracture patients. Those results were similar to the main analysis, therefore, the effect of the protocol violations on our results seems limited.

In both the ankle fracture group as well as in the distal radial fracture group there was a reduction of one radiograph in the reduced imaging group in comparison with the usual care group. This difference was lower than hypothesized (i.e., one, instead of two) in both the ankle fracture and the distal radius fracture group. This might be due to the number of protocol violations. The median number of radiographs in both reduced imaging and usual care was higher in patients with an ankle fracture (usual care median 5, reduced imaging median 4) than in patients with a distal radius fracture (usual care median 4, reduced imaging median 3). This was apparent in our retrospective study as well. Ankle fracture patients received a higher number of radiographs during follow-up (median 3 [Chapter 3]) when compared to distal radius fracture patients (mean 1.8).[12] In the interviews conducted for our implementation study (Chapter 8), more respondents were willing to stop obtaining follow-up radiographs for patients with a distal radius fracture (110/130, 85%) than for patients with an ankle fracture (96/130, 74% [$p < 0.05$]).

Upon further examination of these findings, it would appear that the proposed omission of both the week 6 and 12 radiograph for distal radius fracture patients is deemed safe and could be implemented readily. Whereas for ankle fracture patients, a radiograph at either week 6 or week 12 is highly valued by physicians. Implementation of a follow-up protocol that either omits the week 6 or the week 12 radiograph, therefore, seems feasible. This reduction of one radiograph can be justified with the results of the Warrior trial.

COST-EFFECTIVENESS

Since functional outcomes are not negatively influenced in those with ankle and wrist fractures who were assigned to the reduced imaging group, the question remained whether there was an effect on healthcare costs.

A cost-effectiveness analysis was performed for both patients with an ankle fracture and for patients with a distal radius fracture. In a cost-effectiveness analysis, the cost and effects of an intervention are compared with the cost and effects of a comparator. The effects are typically expressed as Quality-Adjusted Life Year (QALY); the most optimal comparator is usual care. The cost-effectiveness analysis results in the incremental cost of an intervention compared to the comparator per QALY gained.

In the Netherlands, an amount of €20,000 to €80,000 is deemed an acceptable cost per QALY.[21] For both groups, we found a significant reduction in the costs for radiographic imaging in the reduced imaging group (Chapter 5 and 7). For either fracture location, the median reduction in radiographs was 1. This leads to an average cost saving of €48 for both ankle fractures and distal radius fractures. For a single patient this reduction seems rather small. However, since the incidence of these fractures is high, total cost savings for the Dutch population (approximately 17 million inhabitants) are estimated to be €4.1 million annually.[‡] Other costs, including the overall costs, showed no significant differences between the groups. The probability of reduced imaging being cost-effective for QALYs compared to usual care for ankle fractures was 0.45 (45%) at a willingness to pay of €20,000 per QALY. This is considered low. The probability that the reduced imaging follow-up strategy was cost-effective for distal radius fractures was much higher: 0.8 at a willingness to pay of €20,000 per QALY, which increased to 0.9 at a willingness to pay of €80,000 per QALY.

The approach commonly used for a cost-effectiveness analysis (i.e., how much additional costs are needed per QALY gained) is most suitable for trials with either a superiority design, or a trial where there is a distinct difference in QALYs between groups. In our trial, the difference in QALYs between groups was negligible. For patients with an ankle fracture it was -0.008 QALY (95% CI -0.06 to 0.04) and for patients with a distal radius

[‡] Based upon an incidence of 30,000 ankle fractures and 55,000 distal radius fractures

fracture it was 0.025 QALY (95% CI -0.01 to 0.06). Small cost savings and little effect on QALYs may lead to a less accurate cost-effectiveness analysis. This explains why a similar cost saving led to a completely different probability of cost-effectiveness. Another thing we observed was the nullification in costs for radiography by much higher costs for other items, such as absenteeism, presenteeism, hospital admission or surgical fixation of the fracture. As a result, overall costs had large confidence intervals, and did not differ between groups. The fact that these major cost items were comparable does, however, indicate that there were no large financial drawbacks associated with reduced imaging.

When comparing costs of patients with an ankle fracture and a distal radius fracture, we found that having an ankle fracture is more costly than a distal radius fracture for all cost categories. For the cost of secondary care, this might partly be due to a difference in what type of costs were included in this group. For ankle fractures, hospital admission and surgery were included in cost of secondary care. For distal radius fractures, these costs were not included due to an error in our analysis. This makes costs of secondary care in the ankle fracture group and distal radius fracture group less comparable. However, since the number of participants with a distal radius fracture that received surgery was similar (i.e., 21 participants with usual care and 20 participants with reduced imaging) it is unlikely that this has otherwise influenced our results. Other cost groups included the same items and are therefore comparable between those with ankle fractures and those with distal radius fractures. The fact that overall costs of an ankle fracture were more than double the costs of a distal radius fracture might explain why similar cost savings led to a higher probability of cost-effectiveness in those with distal radius fractures. The achieved cost saving of €48 is a relatively larger reduction when overall costs are less.

FUTURE PERSPECTIVES

It would appear that eliminating routine follow-up radiography can be introduced without sacrificing quality of care. However, it will require much effort on the part of healthcare professionals and organizations in order to implement these findings. In order to determine which factors might influence physicians and policymakers to implement our findings, and potential future findings for different fracture locations, more insight in physician behavior was necessary.

In Chapter 8, we evaluated which barriers and facilitators might play a role for physicians to implement the results of the Warrior trial. In short, we found that physicians were more willing to stop obtaining routine radiography if it would lead to financial savings, reduction in time wasted by their patients, and if our study findings were to be adopted in treatment protocols. Familiarity with study findings and adaptation of protocols is known from the literature to be of influence on behavioral change.[22] [23] Educational outreach, such as oral presentations, could inform stakeholders of these results and protocol adaptations.

For medicolegal reasons, alteration of treatment protocols may be the most important facilitator for individual caregivers. Being more cautious than the treatment protocol advises when deemed necessary is far easier to justify, than having to substantiate that omitting elements of a treatment protocol was safe. Medicolegal threats might not be a prime motivator in the Netherlands, but they might play a larger role in other healthcare systems.

CONCLUSION

Routine radiography in the follow-up of patients with an ankle fracture or a distal radius fracture is common practice in Western societies. The analyses contained in this thesis suggest that complications detected during routine radiography for those with ankle or distal radius fractures are rare, and that the number of routine radiographs can be reduced without compromising care. Follow-up radiography after three weeks should be stopped in those with distal radius fractures and can be reduced by at least one in those with ankle fractures. In other words, routine radiography for these patients is low-value care as defined by 'Choosing Wisely'. Healthcare professionals and organizations should focus their attention on how to implement these findings on a national level. Broadening the selection of patients to include other types of fractures or fractures at different locations would also help to implement our findings on a larger scale. Additionally, future studies are necessary in order to determine which patients might benefit from close fracture monitoring.

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