An Early Cost-Effectiveness Analysis of a New Continuous Compartment Pressure Monitoring Device in Tibial Fracture Patients Who Are at Risk of Developing Acute Compartment Syndrome (ACS)

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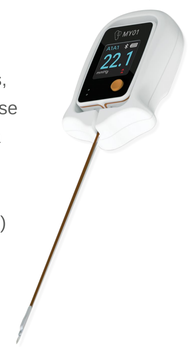
BACKGROUND AND OBJECTIVES

Acute Compartment Syndrome (ACS) is a serious and painful health condition caused by bleeding and swelling within a muscle compartment that needs to be urgently treated in hospital [1]. For patients at risk of developing ACS after receiving treatment for a complex tibial fracture, standard care monitoring is often clinical opinion and single-point pressure monitoring, which relies on regular checking and patient reported symptoms that may be compromised by impaired consciousness. This has previously led to delayed or incorrect diagnoses, which can allow for extensive muscle necrosis to develop or an unnecessary fasciotomy performed.

The treatment for ACS ranges depending on the scale of muscle necrosis and can include resource-intensive and invasive procedures, which in turn can increase the risk of complications [2-5]. Each of these procedures and complications are costly to the payer and can have a significant impact on health and quality of life.

The aim of this early study was to determine the potential cost-effectiveness of a new continuous pressure monitoring device (MY01) in patients treated for a tibial fracture who are at risk of developing ACS. The MY01 device, as shown on the right, , is a microsensor inserted into the patients' limb via a needle and shares pressure reading data with the care team, which is stored as de-identified.



METHODS

A decision-tree model (Figure 2) was developed with a UK NHS perspective to capture outcomes in the first 60 days after a tibial fracture, when patients are at highest risk of ACS. For each of MY01 and standard care, a hypothetical cohort of 1,000 patients was developed receiving ACS monitoring methods. Patients first moved through the model according to the sensitivity and specificity of each method.

Patients then moved to one of five ACS outcome groups, characterised by the scale of muscle necrosis and treatment course (Table 1), or to standard fracture care if they receive a true negative diagnosis. Movement to these states was dependent on the effectiveness and speed of the diagnostic method. The treatment could include resource-intensive and invasive procedures, namely fasciotomy, skin grafts, limb salvage and amputations, which in turn increased the risk of complications including infection, non-union, amputation and death [2-5]. Average costs, utilities and hospital length of stay were applied to the ACS outcome groups depending on the clinical events that can occur within each group. In each ACS outcome group, except for Gr5: Immediate amputation, a risk of amputation was applied as an additional further complication.

Table 1: ACS Outcome Groups

Group	Description
Gr1. Incorrect ACS diagnosis and fasciotomy	A false positive result. Patients do not have ACS, but are treated with fasciotomy unnecessarily. Primary closure or 1-2 day delayed primary.
Gr2. Minimal necrotic muscle	The fastest and ideal ACS diagnosis. Patients have minimal necrotic muscle, with or without pie crusting. Standard fasciotomy is used.
Gr3. Minimal necrotic muscle with complications	A slight delay in ACS diagnosis. Patients have minimal necrotic muscle using complexes closure methods associated with high risk of infection.
Gr4. Complex and extensive muscle necrosis	A significant delay in ACS diagnosis. Patients have extensive muscle necrosis requiring limb reconstruction (limb salvage) a high chance of complications.
Gr5. Immediate amputation	A substantial delay or missed ACS diagnosis. Muscle necrosis is extensive enough that immediate amputation is required.

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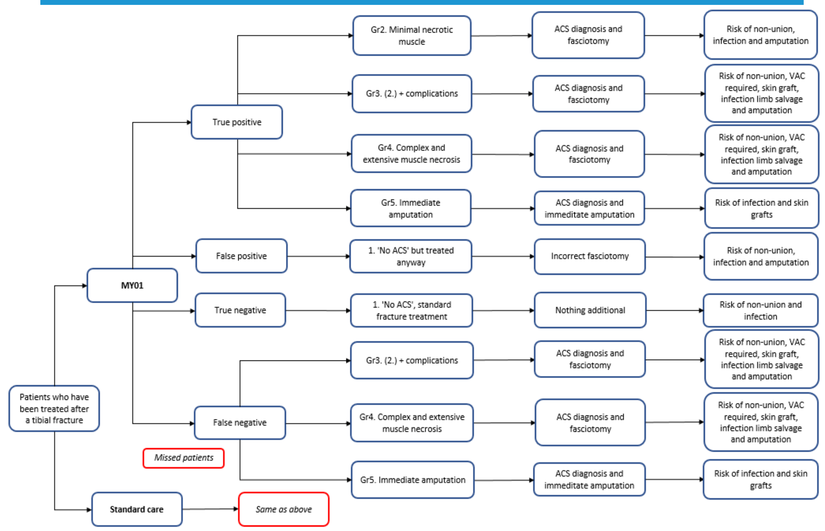
Figure 2: Model structure



The key model parameters are displayed in Table 2. Parameter inputs were obtained from UK-specific published literature and clinical opinion where possible. The sensitivity and specificity parameters for MY01 were sourced from McQueen (2013) and recent MY01 trial data [6,10]. The sensitivity and specificity values for standard care monitoring methods were sourced from Janzig (2001) [7]. Sensitivity and specificity determine the accuracy of a test at determining a positive diagnosis and a negative diagnosis respectively. The proportion of patients with a true positive result entering each ACS outcome group for MY01 was assumed to be equal to the standard care proportions used [3,8]. This assumption was likely conservative, as recent unpublished trial outcomes indicate higher proportions of patients are entering less severe ACS outcome groups after a true positive result with MY01. The proportion of patients with a false negative result entering each ACS group was equal between MY01 and standard care in the analysis, based on the assumption that if a patient was “missed”, the detection method used would have no impact on the level of muscle necrosis that could develop [9].

The rates for different clinical events within each ACS outcome group were primarily sourced from the published literature for ACS [3-5,12]. ACS outcome proportions were calculated from requested Predicting Acute Compartment Syndrome and Trauma Quality Programs data [3,8,9]. For the base-case analysis, proportions between MY01 and standard care were assumed to be equal. Costs and resource use within the model were primarily sourced from the National Cost Collection 2020/21, PSSRU 2021 and the published literature [11,13-14]. For all outcome groups, mortality risk was set to equal UK background mortality except for Gr5: Immediate amputation, which was set higher in the model [15-16]. Quality of life parameters were calculated by applying reported clinical event disutilities, weighted using the aforementioned clinical rates, to UK population norms [17-20]. Length of stay was included in the model solely as a model output and has no further bearing on the results.

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Table 2: Key model input parameters

Parameter	MY01		Standard care	
Sensitivity	94.0% [6,10]		89.0% [7]	
Specificity	98.0% [6,10]		65.0% [7]	
ACS outcome	***True positive***	***False negative***	***True positive***	***False negative***
Gr2.	39.5% [3,8]	0% [9]	39.5% [3,8]	0% [9]
Gr3.	43.8% [3,8]	72.4% [9]	43.8% [3,8]	72.4% [9]
Gr4.	11.3% [3,8]	18.7% [9]	11.3% [3,8]	18.7% [9]
Gr5.	5.4% [3,8]	8.9% [9]	5.4% [3,8]	8.9% [9]
Cost per use	£2,738.50 [10,11]		£64.22 [2,11]	

RESULTS

Results are presented for a 60-day time horizon in Table 3. The results suggest that the systematic use of MY01 as an ACS-detection method is cost-saving for a post-tibial fracture treatment population when compared with standard care detection methods. The primary saving is associated with the reduction of false positive diagnoses (unnecessary interventions), which alone outweighs the cost of using MY01. The use of MY01 is estimated to result in an incremental QALY gain of 0.01 over 60 days when compared with standard care. DSA showed that the results were most sensitive to the specificity of standard care and MY01, the cost per detection method and the cost of fasciotomy.

Table 3: Model results

	MY01	Standard care	Incremental
Total cost per person	**£5,532**	**£5,772**	**-£240**
Total QALYs per person	**0.14**	**0.13**	**0.01**
Incremental cost-effectiveness ratio (ICER)			**Dominant**
Net monetary benefit			**£366.79**
Hospital length of stay per person (no bearing on the cost or QALY outcomes)			**-4.02 days**

CONCLUSIONS

This early analysis suggests that MY01 could be a cost-effective diagnostic option for patients who have received tibial fracture treatment and are at risk of developing ACS in the UK NHS, and potentially other healthcare systems. It was estimated that the intervention was associated with higher specificity and sensitivity than current methods, reduced length of hospital stay, resource and cost savings, and improved patient outcomes. A key driver of all cost outcomes in the model were the number of patients that avoided costly false-positive diagnoses.

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