InterDry Value Assessment

Cost-effectiveness Analysis of the Treatment of Intertrigo with InterDry vs. Standard of Care in a UK Community Setting

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Contents

Abstract

Background

Intertrigo is skin inflammation caused by skin-to-skin friction typically found in areas such as armpits, groin and under the breasts. Intertrigo is most prevalent among obese populations and causes symptoms such as itching, burning, unpleasant odour and pain. Intertrigo may lead to complications such as bacterial and fungal infections. InterDry is a medical fabric intended for skin fold management and thereby resolve all symptoms of intertrigo.

Objective

To evaluate the cost-effectiveness of InterDry in the management of intertrigo compared to the Standard of Care (SoC) as recommended by the PCDS in a UK care home setting.

Methods

A simple deterministic markov decision model was developed to project the 1-year cost of management with InterDry (arm 1) vs. Standard of Care (arm 2) respectively. To reflect the resolution and dynamics of Intertrigo, the 1-year horizon was divided into 74 cycles with a cycle length of 5-days. The model contained two health states: 1) “intertrigo” in which patients had not yet been successfully resolved and would subsequently need to continue management and 2) “resolved” in which patients had been successfully resolved and would remain healthy. The cost input in the model were the direct product costs and nurse time for applying the treatment. The transition probabilities were obtained from the existing literature.

Results

InterDry is a cost-saving treatment for intertrigo which costs £ 0.32 less than standard of care per resolved case of intertrigo over a 1-year horizon. In practice, the InterDry cost savings are likely to be substantially larger because complications such as bacterial infections are not included in the current model along with further health benefits gained by successfully resolving intertrigo.

Background

Intertrigo (intertriginous dermatitis) is a type of skin inflammation caused by friction from opposing skin surfaces (skin-to-skin friction) primarily found in the inframammary, axillary, and inguinal folds [1, 2]. The most common symptoms of intertrigo are itching, burning, unpleasant odour, and pain. The symptoms of intertrigo occur as a result of the cutaneous friction which increases heat, moisture and maceration while simultaneously decreasing air circulation in the affected areas. If Intertrigo is left untreated, there is an increased risk of secondary complications such as bacterial and fungal infections.

Due to the high recurrence rate of the condition, the physiological symptoms of intertrigo often become a prevailing part of patients' lives thereby posing a burden on psychological and mental health. As an example of such effects, in-patient nurses report patients being embarrassed, overly self-conscious, distressed, and having a low mood/showing signs of depression [3].

The prevalence of intertrigo is positively correlated with the degree of obesity [4, 5]. Boza et al. found a prevalence of 44.7% among obese Brazilians, and Al-Mutairi found a prevalence of 22.2% among overweight and obese Kuwaitis [4, 5]. Other risk factors include age, hyperhidrosis, immobility, self-neglect, diabetes mellitus and poor hygiene [5-8].

To our knowledge, no existing studies document the prevalence or incidence of intertrigo in the UK. However, the National Prevalence Measurement of Quality of Care (LPZ) in The Netherlands estimate that 5.4% of the patients in the general hospital sector suffered from Intertrigo in the Netherlands in 2014 [9]. Furthermore, in 2015 6.7% of individuals in the care home sector suffered from Intertrigo [8, 10]. According to the OECD, the UK has an obesity rate nearly double that of the Netherlands, with 26.2% and 13.6% respectively [11]. Given the direct correlation between Intertrigo and obesity, the Dutch figures can be considered conservative when compared to the UK.

Introduction

The Primary Care Dermatology Society (PCDS) recommends Daktacort (1% hydrocortisone, 2% miconazole) as a first-line medical treatment of intertrigo in the UK to reduce inflammation and treat possible fungal infection. Subsequently, in the case of severe inflammation, short-term treatment using Trimovate cream is recommended [12]. The LPZ reports that 29.4% of intertrigo patients in care homes lived with unresolved cases of intertrigo for more than a year [9].

InterDry is a medical fiber containing silver with a regulatory class 1 approval from the FDA and CE mark Class III in EU. It is developed to manage and resolve symptoms of intertrigo with and without infection through management of the causal factors leading to intertrigo. InterDry wicks away moisture, reduces friction, and provides broad-spectrum antimicrobial action using ionic silver. InterDry has been tested with promising results in multiple unpublished case studies [13], as well as a single non-controlled multi-site trial of 25 subjects (19 with complete data) with hard-to-treat intertrigo and candidal intertrigo [14].

Methods

This section provides an overview of the methods used to build and derive the health-economic model and subsequent cost-effectiveness results.

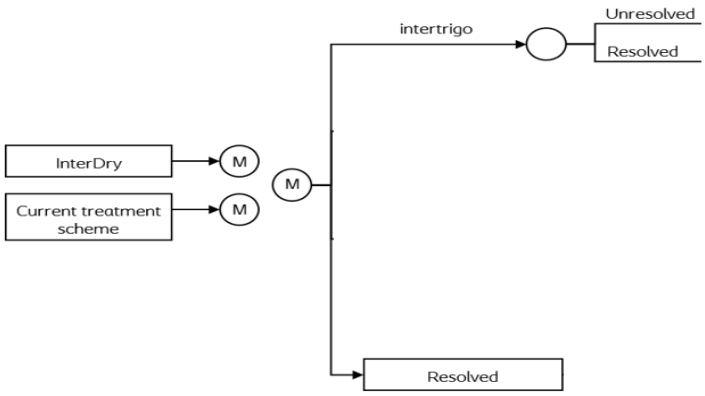
Model

We analysed the intertrigo disease pathway (with associated costs) under management with InterDry and SoC using a markov chain model inspired by a previous model [8]. The model includes two states: intertrigo (non-healthy) and resolved (healthy). Resolved is an absorbing state without symptoms of intertrigo or need for further interventions.

The model simulates resolution of symptoms with SoC and InterDry and compares the cost and effect of each of these arms. The simulation runs for 74 periods of 5 days, which amounts to a full modelling horizon of 1 year. After each cycle of 5 days, the unresolved cases of intertrigo will pass on to a successive cycle of first-line intervention. Resolved cases will remain in the resolved state. Due to the short modelling horizon, the model does not include any discounting factors.

The diagram below presents an overview of the model. Each arm is presented at the leftmost part of the diagram. In both arms, all patients enter the model in the intertrigo health state and can hereafter either stay in the intertrigo health-state or move to the resolved health state. The transition probabilities into each health-state are allowed to differ across arms and will be described below.

Figure 1 - State diagram



Standard of Care

The analysis is performed from a UK care home perspective, with SoC based on guidelines from the PCDS [12]. According to PCDS guidelines, treatment should consist of Daktacort cream *(Hydrocortisone 1% and Miconazole 2%)* or Trimovate *(Clobetasone butyrate 0.05%, Oxytetracycline 3% and Nystain 100.000 units per gram)* depending on the severity of the intertrigo. In the absence of efficacy data on Trimovate, we defined SoC as treatment with Daktacort alone [12].

Input variables

Costs

The price of Daktacort was derived from Drug Tariff, with £2.42/30g corresponding to a unit price of £0.0807/g. Utilisation of gauze or pillow cases has not been included. The tariff for nursing time was sourced from the Royal college of nursing. It was assumed that intertrigo would primarily be managed by a band five nurse. The subsequent hourly tariff was calculated as an average of the different band 5 levels and estimated to be £12.88/hour [15]. All unit costs are presented in table.1.

Utilisation of products and associated nursing time

The usage of InterDry was estimated as an average of the actual use from the patients included in the multisite feasibility study (MSF) [14]. The study found an estimated use of InterDry of 1656 cm^2/cycle. The usage of Daktacort was estimated from the pre-study treatment as at least 1 bottle per week and subsequently converted to reflect the five-day treatment cycle [14]. The use of Daktacort was estimated at 21.43 g/cycle.

Nursing time associated with the management of intertrigo using either InterDry or SoC was estimated based on input from 4 tissue viability nurses. The estimated nursing time covers cleaning of the affected area and applying the given intervention. The daily nursing time associated with InterDry and SoC was estimated as being 15 and 20 minutes, respectively [8].

Transition probabilities

The treatment effect is incorporated into the model through the transition probabilities, as they define the relative probability of changing state. Transition probabilities of the two respective treatments in the model are extrapolated from literature and referred to hereunder as resolution rates. The transition probabilities are presented in table.1.

Daktacort

The resolution rate of Daktacort was calculated using data from a double-blinded comparative study between hydro-cortisone, and hydro-cortisone with miconazole (Daktacort) [16]. The study endpoints included physicians' assessment of four key symptoms and a patient reported binary response to 'cured'. All endpoints were measured after 14 days. The physicians' assessments of 'cure' and 'minor residual lesions' were both taken to equal resolution [16]. Due to the subjective nature of assessing erythema and pruritus levels, the patient reported response to being cured was also utilised. The mean resolution rate was taken from the physician and patient responses and subsequently converted to a 5-day equivalent resolution rate. This 5-day resolution rate was then used in the model.

InterDry

The resolution rate of InterDry was extrapolated from the clinical investigation report of the multisite feasibility study (MFS) [14]. The trial measured the efficacy of InterDry over a 5-day period. For use in the markov model, successful resolution was defined as full

resolution of all of the following five symptoms; erythema, maceration, denudement, satellite lesions and itching / burning.

Table 1 - Input variables

		Value (SD)	Reference
Resolution rate (transition prob) /5 days			
InterDry – resolution%		73.33	[14]
Standard of care – resolution%		36.17	[16]
Input Variable, unit consumption /5 days		Value (SD)	
InterDry		1,656(+-149) cm^2	[14]
Daktacort		21.43g	[8]
Nursing time (Band 5) InterDry		5 x 15 min	[8]
Nursing time (Band 5) Standard of care		5 x 20 min	[8]
Input variable, unit price			
InterDry		£0.01854 /cm^2	
Standard of care		£0.0807 /g	[17]
Nursing time (band 5)		£12.88(+-1.34) /hour	[15]

Results

Table 2 shows the cost of resolving an average case of intertrigo with SoC and InterDry. The cost per fully resolved case of intertrigo is £64.15 for SoC and £63.74 for InterDry. As indicated from the results, a small potential cost-saving could be achieved with InterDry, suggesting it to be a cost-effective and cost-saving intervention.

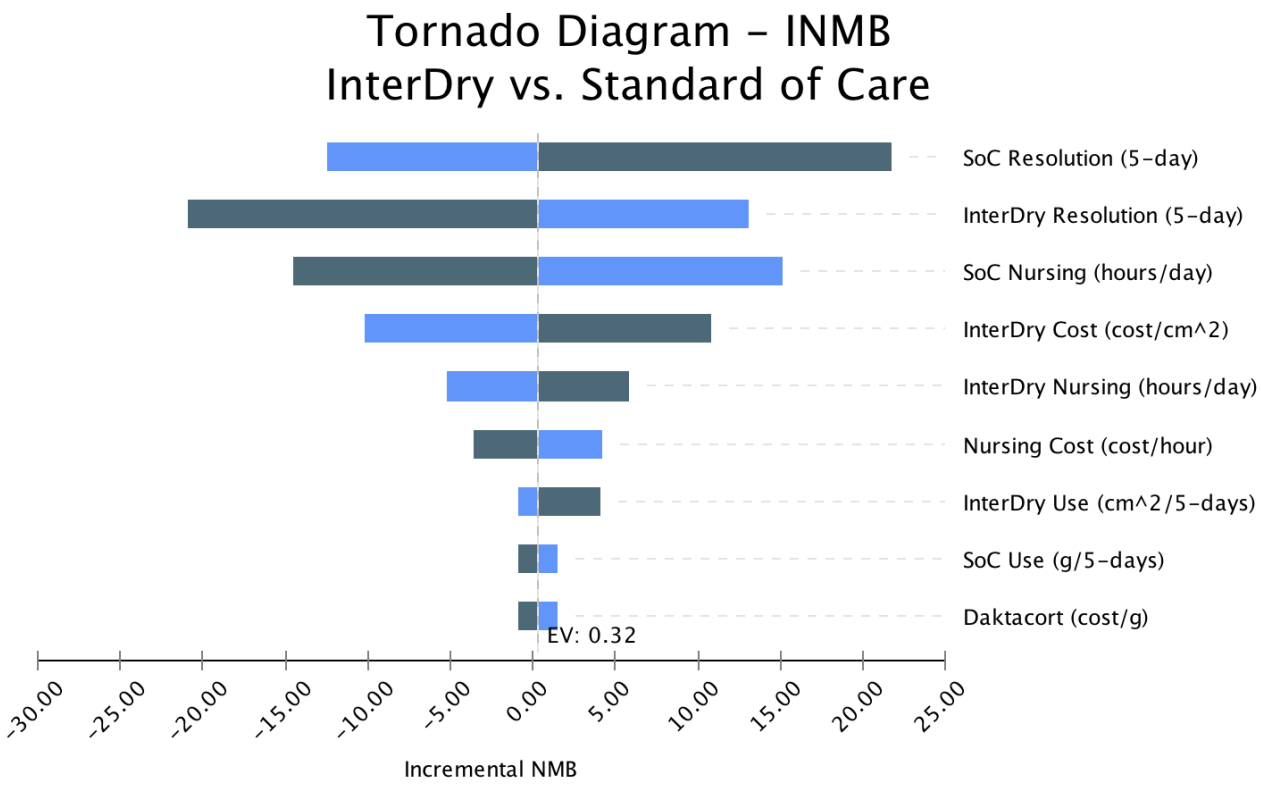
Table 2 - Results

	Cost (GBP)
SoC	£64.15
InterDry	£63.83
Incremental cost	£-0.32

The tornado diagram in figure 2 shows the incremental net monetary benefit of InterDry vs. Standard of Care, where the vertical striped bar represents the outcome of the model (£0.32). The blue bars represent the upper values and the grey represent the lower values of the sensitivity analysis.

The results of the 1-way sensitivity analysis (tornado diagram), on Incremental Net Monetary Benefit reveal that the three most impactful variables are the transition probabilities, and the nursing time associated with either SOC or InterDry. In absence of detailed data describing the variables, the sensitivity analysis is carried out with an assumed standard deviation of 25% in all variables.

Figure 2 - Sensitivity Analysis



Discussion

The main finding of this analysis is that using InterDry for management of intertrigo can lead to cost savings in management of intertrigo, compared to the current SoC. However, this study has several limitations due to the scarcity of quality evidence on intertrigo in general as well as on the existing treatments of intertrigo and the results should therefore be interpreted with this in mind.

In order to present a plausible result, the model is based on conservative assumptions and the most important ones are discussed hereunder.

Firstly, a potential weakness of the analysis is the simple nature of the treatment pathway. The model only allows for first-line treatments (SoC and InterDry) and neither includes further treatments nor complications. Relevant non-included subsequent treatments are the use of Trimovate, antibiotics, oral antifungal therapy and, in some cases, surgery to remove excess skin [12]. These 2nd line treatments were not included due the lack of available data on their efficacy and rate of use for intertrigo. It is noted that all of these management alternatives are are relatively costly options. For instance, Trimovate (which is recommended when inflammation does not subside or worsen) is priced approximately five times higher than Daktacort on Drug Tariff [12, 18]. Furthermore, Trimovate potentially also require one GP consultation before initiation of treatment. In conclusion, adding the relevant subsequent (2nd line) treatments into the model is likely to lead to even greater cost savings from management of skinfolds with InterDry than illustrated in the current model. This is due to the faster resolution of intertrigo with InterDry and consequently less need to escalate treatment to more costly options.

Secondly there is also a lack of comparable evidence on the resolution rate of the two interventions. The data on the efficacy of Daktacort for treating intertrigo originates from a study among an average population of patients with intertrigo. In contrast, the patients managed in the MSF-study (examining the efficacy of InterDry) was selected among a population with hard-to-treat intertrigo. As such, the patients included in the MSF study had already received unsuccessful treatment by steroid and anti-fungal creams with an average history of intertrigo treatment of 226 days. Because of the hard-to-treat patients in the MSF-study, the efficacy of InterDry may be underestimated [8, 14].

Thirdly the cost-effectiveness model does not include downstream health benefits gained by receiving a more effective skin fold management and faster resolution of intertrigo. The only impact of not being successfully resolved in the model, is that the patient requires another cycle of product costs combined with associated nursing time for the application of the products. Adding the cost associated with the entire patient pathway (such as bacterial and fungal infections) would potentially increase the savings tied to fast resolution of intertrigo.

Conclusion

InterDry is a cost saving strategy for resolving symptoms of intertrigo compared to SoC in a UK care home setting, given the assumptions mentioned. The study has several limitations and additional data of intervention efficacy and the economic burden of intertrigo is needed in order to make a more precise estimate.

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