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Full length article

Synthetic osmotic dilators (Dilapan-S) or dinoprostone vaginal inserts (Propess) for inpatient induction of labour: A UK cost-consequence model

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ABSTRACT

Objective: To estimate the costs of synthetic osmotic dilators (Dilapan-S) compared to dinoprostone vaginal inserts (Propess) for inpatient induction of labour (IOL).

Study design: A population-level, Markov model-based cost-consequence analysis was developed to compare the impact of using Dilapan-S versus Propess. The time horizon was modelled from admission to birth. The target population was women requiring inpatient IOL from 37 weeks with an unfavourable cervix in the UK. Mean population characteristics reflected those of the SOLVE (NCT03001661) trial. No patient data were included in this analysis. The care pathways and staff workload were modelled using data from the SOLVE trial and clinical experience. Cost and clinical inputs were sourced from the SOLVE trial and peer-reviewed literature. Costs were inflated to 2020 British pounds (GBP, £). Outcomes were reported as an average per woman for total costs and required staff time (minutes) from admission for IOL until birth. The model robustness was assessed using a probabilistic, multivariate sensitivity analysis of 2,000 simulations with results presented as the median (interquartile range, IQR).

Results: Dilapan-S was cost neutral compared to Propess. Midwife and obstetrician times were decreased by 146 min (−11%) and 11 min (−54%), respectively. Sensitivity analysis showed that in 78% of simulations, use of Dilapan-S reduced midwife time with a median of −160 min (IQR −277 to −24 min). Costs were reduced in 54% of simulations (median -£33, IQR -£319 to £282).

Conclusions: The model indicates that adoption of Dilapan-S is likely to be cost-neutral and reduce staff workload in comparison to Propess. Results require support from real-world data and further exploration of Dilapan-S is to be encouraged.

Introduction

Rates of induction of labour (IOL) in the United Kingdom (UK) increased from 20% of deliveries in 2008 to 33% in 2018 [1]. Possible reasons may be the increasing rates of maternal co-morbidities and evidence that IOL at 39 weeks reduces the risk of caesarean section and perinatal death [1–4]. A UK cost-utility analysis of nulliparous women of advanced maternal age found that IOL at 39 weeks was cost saving while not increasing caesarean sections in comparison to expectant management [5,6]. Expanding IOL has the potential to overwhelm maternity units who are already struggling with staff shortages and delays leading to longer inpatient stays [7,8]. Overburdened maternity units may negatively impact on women's birth experiences and potentially on obstetrics outcomes [8,9].

Optimising hospital processes for IOL and birth presents an opportunity for reducing staff workload. A recent meta-analysis reported that no single cervical-ripening agent (CRA) was found to be superior in efficacy and safety [10]. As such, the choice of CRA may come down to preference, staff burden, ease of use, and cost. In regards to staff workload, cervical ripening with prostaglandins necessitates extended fetal and maternal monitoring during IOL due to the risk of uterine hyperstimulation, a risk that is reported by National Institute of Health and Clinical Excellence (NICE) to be reduced with mechanical methods [11–13]. In addition, differences in the need for analgesics or required

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re-administrations of the CRA can also impact resource use and staff workload [14].

The 2008 NICE guidance on IOL stated that vaginal dinoprostone was the preferred method of IOL and advised against the routine use of mechanical ripening methods [11]. In the updated NICE guidance from 2021 these recommendations were revised, and further cervical-ripening agents were recommended, including the mechanical synthetic osmotic dilator (commonly known as Dilapan-S) [9]. A recent UK randomised controlled trial including 674 women (SOLVE trial, NCT03001661) comparing Dilapan-S to Propess demonstrated that both methods have similar efficacy in terms of vaginal deliveries with a higher cervical-ripening success rate after the first-ripening attempt with Dilapan-S [14]. With this work, we assessed how the choice of CRA could impact costs and resource use for women requiring cervical ripening for IOL.

Methods

This is a health-economic assessment developed in compliance with guidance development recommendations from NICE and using the cost-consequence approach [15]. The model does not use any data from real-life patients, but instead uses a simulated cohort of patients, the mean characteristics of whom reflect those of the UK IOL population.

Target population and comparators

The population was a cohort of nulli- and multiparous women with an unfavourable cervix (Bishop score of 6 or less) eligible for IOL who were not contraindicated to receive prostaglandins. All women were assumed to receive either Dilapan-S (Medicem s.r.o) or Propess (Ferring Pharmaceuticals Ltd.). Brand names were used throughout because no common generic names are used in the UK for these products. These methods for IOL were chosen because Propess is widely used throughout the UK and synthetic dinoprostone was the only method recommended by NICE until recently [11], and Dilapan-S was added to latest NICE guidance on IOL [9]. Moreover, these methods are the comparators in the SOLVE trial (NCT03001661) that is a UK-based, randomised controlled trial [14].

Choice of clinical outcomes

We selected clinical outcomes that were relevant from the start of cervical ripening until birth, including caesarean section rates. This work focussed on assessing hospital costs and staff workload associated with the type of CRA given for IOL. Since this is an economic analysis to complement the SOLVE trial, and it closely models the population of this trial, clinical outcomes were taken from the original clinical-trial publication [14]. No postnatal or preference-based outcomes were included in this work.

Estimating resources, costs & measurement of effectiveness

A comprehensive, structured literature review of PubMed-indexed literature published between January 2010 and June 2021 was performed to identify relevant data and supplemented by manual searches of PubMed and Google Scholar. Search strings used to retrieve publications from PubMed are given in the supplementary Table S1. Resource parameters and costs were sourced from identified peer-reviewed literature. A consensus of IOL protocols of each of the maternity units of our clinical authors (KFW, JKG and SZ) was established, especially to determine staff-time and monitoring requirements during IOL because this information was not readily available in peer-reviewed literature or in local and national guidance (see supplementary Table S2). Clinical safety and efficacy input parameters are given in Table 1 and cost input parameters are given in Table 2. Costs were all taken from UK sources and were inflated, if required, from source year to 2020 GBP.

Table 1
Clinical safety and efficacy parameters.

	Dilapan-S	Propess
Average numbers of CRA administrations, N (SD)	1.56 (0.16)	1.74 (0.17)
Primary caesarean birth, nulliparous women, rate (SD)	0.416 (0.097)	0.359 (0.094)
Primary caesarean birth, multiparous women, rate (SD)	0.206 (0.079)	0.277 (0.088)
Oxytocin augmentation, rate (SD)	0.627 (0.095)	0.393 (0.096)
Spontaneous delivery following induction, rate (SD)	0.383 (0.057)	0.393 (0.077)
Uterine hyperstimulation with fetal heart-rate changes, rate (SD)	0 (0)	0.043 (0.04)
Any mild opioids during cervical ripening, rate (SD)	0.214 (0.080)	0.439 (0.097)
Any strong opioids during cervical ripening, rate (SD)	0.062 (0.047)	0.175 (0.074)
Epidural during cervical ripening, rate (SD)	0.003 (0.011)	0.009 (0.019)
Entonox during cervical ripening, rate (SD)	0.190 (0.019)	0.086 (0.009)
Any mild opioids during labour, rate (SD)	0.053 (0.044)	0.068 (0.049)
Any strong opioids during labour, rate (SD)	0.187 (0.076)	0.157 (0.071)
Epidural during labour, rate (SD)	0.555 (0.097)	0.516 (0.098)
Entonox during labour, rate (SD)	0.588 (0.059)	0.549 (0.055)
General anaesthesia during labour, rate (SD)	0.048 (0.042)	0.024 (0.030)
Time admission to induction, hours (range)	0.95 (0.60–1.60)	0.60 (0.40–1.10)
Time admission to amniotomy, hours (range)	44.20 (26.9–67.1)	44.60 (23.80–72.00)
Time admission to birth, hours (range)	52.90 (35.80–78.60)	45.30 (24.70–74.60)
Time amniotomy to birth, hours (range)	10.10 (5.90–15.20)	9.30 (4.80–13.40)
Ripening time, hours (range)	21.20 (16.10–24.80)	24.40 (13.90–34.70)

All clinical input parameters were taken or calculated from the published SOLVE trial [14]. Accuracy of two decimal points was used for N events and times; three decimal points were used for rates. CRA, cervical-ripening agent; SD, standard deviation.

Choice of model

We developed a cost-consequence model in compliance with NICE development recommendations [15], in Microsoft™ Excel™, estimating the costs and the consequence on staff workload associated with different methods of cervical ripening as part of IOL. A UK hospital perspective was taken with the time horizon of the model from the admission to hospital for preinduction cervical ripening to birth. Due to the short time horizon of a few days, no discounting has been applied to the costs.

The model was designed as a Markov model (Fig. 1), with the transition probabilities dependent on both the probability to experience the event and the average duration in each birth-related state, given as times and incidences reported by the SOLVE trial [14]. Model outcomes are reported as a calculated average per woman over any cohort of at least 100 women. Clinical outcomes comparing Dilapan-S to Propess have been taken from the original SOLVE trial publication [14].

The model accounted for the three stages of an in-hospital, labour-induced birth: (1) patient preparation, (2) insertion of the cervical-ripening agent and ripening time, and (3) induced labour or active labour until birth. Before CRA insertion and labour induction, we included waiting-time states for the time that the woman is technically ready for the next step in the process but needs to wait for staff and resources to become available. The modelled patient states are illustrated in Fig. 1. The process of IOL is mostly midwife led in the UK; the midwife manages all interventions and monitoring. Monitoring was required after CRA insertion and was repeated for Propess every-six hours, additional

Table 2
Cost parameters.

	Value	Source
Cost Dilapan-S, GBP (SD)	44.65 (4.47)	Communicated by sponsor
Cost Propess, GBP (SD)	33.00 (3.30)	BNF
Cost oxytocin, GBP (SD)	2.67 (0.27)	BNF
Cost mild opioid, per administration, GBP (SD)	0.05 (0.01)	BNF
Cost strong opioid, per administration, GBP (SD)	0.46 (0.05)	BNF
Cost Entonox, per-patient per minute, GBP (SD)	0.35 (0.04)	6L/minute flow rate*
Cost epidural, per administration, GBP (SD)	415.45 (41.55)	[16]
Cost general anaesthesia, per administration, GBP (SD)	1130.80 (113.08)	[16]
Cost pre-natal ward, per hour, GBP (SD)	29.26 (2.93)	[17]
Cost labour and birth room, per hour, GBP (SD)	66.51 (6.65)	[17]
Cost clinician (Band 8a), per hour, GBP (SD)	47.00 (4.70)	[18]
Cost midwife (Band 5), per hour, GBP (SD)	38.00 (3.80)	[18]
Cost vaginal birth, GBP (SD)	49.31 (4.93)	[19]
Cost caesarean section, GBP (SD)	1,754.92 (175.49)	[19]

* Estimated from wholesale price. All input values were given to a two decimal-point accuracy where possible. BNF, British National Formulary. CRA, cervical-ripening agent; SD, standard deviation. Costs are given in 2020 British pounds (GBP). BNF, Joint Formulary Committee (2022); British national formulary 83; London: BMJ Publishing and the Royal Pharmaceutical Society.

monitoring was considered for events of hyperstimulation and when there was a need for strong opioids or epidurals. Obstetrician time was considered only for the prescription of Propess, strong opioids, and epidurals; and 30 min of physician time was considered in the event of hyperstimulation with fetal heart-rate changes. Physician times during and after the stage of active labour were not modelled because these were assumed to be comparable between Dilapan-S and Propess. Times required by both types of maternity staff are given in the supplementary Table S2.

Two assumptions were made regarding monitoring and staff-time requirements. First, we assumed no increased monitoring time for the risk of hyperstimulation during IOL using Dilapan-S, which was specifically recommended for the PGE2 insert in the latest NICE guidance [9]. Therefore, a shorter period of monitoring surrounding the insertion and a less frequent monitoring after insertion was assumed for Dilapan-S (Table 2). Second, all staff-time parameters were derived from a consensus of our clinical authors, as required inputs were not available in published literature.

Analytical methods

To test the robustness of the results, a multivariate probabilistic sensitivity was performed. Each value was sampled using the variance, which, in case it was not available, was assumed to be at 10% of the base-case value. Patient times were drawn from lognormal distributions while costs and incidences were sampled from a normal distribution. The sensitivity analysis calculated 2,000 simulations, mimicking a subset of 2,000 different settings for resources, costs, and clinical outcomes. The results of the sensitivity analysis were reported as the median value, the interquartile range, and the fraction of simulations that were in favour of Dilapan-S over Propess.

Scenario analysis

In the SOLVE trial, it was observed that waiting times occurred between intervention states [14]. In the presented Markov model, we included waiting states for when the woman needed to wait (Fig. 1). To estimate the impact of the waiting times on the overall results, a scenario analysis was performed that excluded all costs and resources associated with those waiting states by setting their duration to zero.

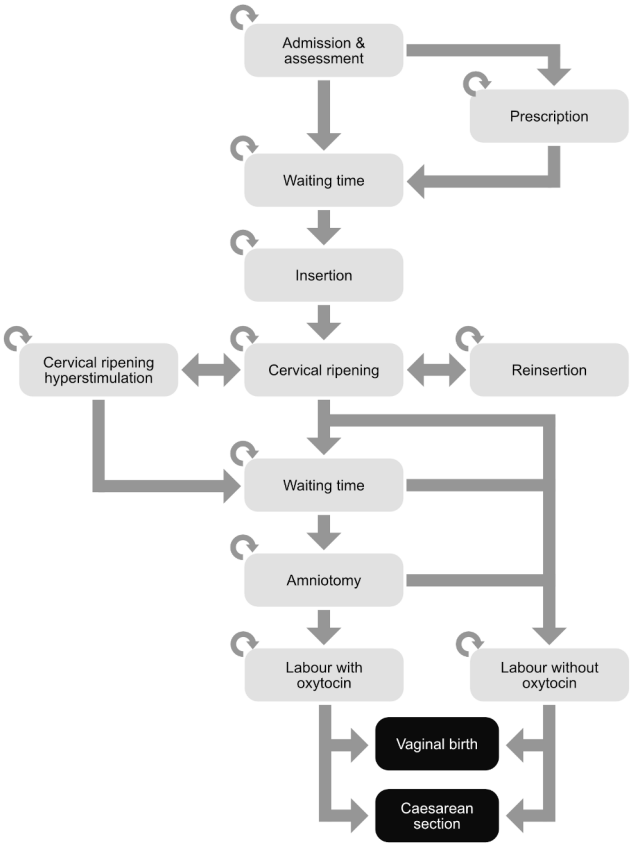

Fig. 1. Schematic representation of the Markov model of the inpatient process of IOL until birth. All women entered the model at the admission and assessment state. Women receiving Propess required a prescription while women receiving Dilapan-S were exempt and moved directly to the waiting state for insertion. All women received either Propess or Dilapan-S until these devices were removed or fell out and, after waiting for staff and resource availability, labour was initiated. Women could receive an amniotomy with or without subsequent oxytocin augmentation for labour. The final states were either vaginal birth or birth via caesarean section. At all intermediate states, women could move to the caesarean section state (not illustrated here for simplification purposes).

Results

The model estimated that the cost difference between Dilapan-S and Propess was negligible, with the former saving around £6 over the course of admission to birth (Table 3). The total induced-birth costs were £3,525 for Dilapan-S and £3,531 for Propess. The distribution of the costs was different between both cervical-ripening agents, with higher

Table 3
Cost by ripening agent and phase of birth.

	Dilapan-S	Propess	Difference
Cost admission	£ 33	£ 58	-£25
Cost ripening*	£ 1,785	£ 1,917	-£132
Cost labour	£ 1,708	£ 1,556	£151
Total	£ 3,525	£ 3,531	-£6
Total without waiting times	£ 2,654	£ 2,662	-£8

*Waiting time included. All costs are given in 2020 British pounds (GBP) and rounded to the nearest pound.

costs incurred for Propess during cervical ripening and for Dilapan-S during labour. In the scenario analysis excluding waiting times, total costs did decrease but the cost difference between CRAs did not change substantially to the base case (Table 3).

Regarding the estimated staff workload, 1,334 min of midwife time were calculated for Propess and 1,187 min for Dilapan-S, corresponding to a reduction of 147 min (−11%) of required midwife time in favour of Dilapan-S. The majority of time saved for Dilapan-S in comparison to Propess was accrued during cervical ripening: 211 min less time was estimated for the midwife during this stage. In contrast, the Dilapan-S group experienced fewer spontaneous vaginal deliveries, which increased the length of stay in the maternity unit of this group with the associated resource consumption. The required obstetrician time for women was 21 min and 10 min with Propess and Dilapan-S, respectively. This difference of −11 min (−54%) was mostly due to Propess requiring a prescription in whereas Dilapan-S did not.

Modelled outcomes for vaginal delivery and caesarean section were similar to the inputs taken from the SOLVE trial, which is an indication that the Markov model is an accurate representation of birth outcomes. In our model, 31.6% and 30.5% of women in the Propess and the Dilapan-S arm, respectively, required a caesarean section while the SOLVE trial reported 32.0% and 31.7% expected caesarean sections for Propess and Dilapan-S, respectively.

The sensitivity analysis confirmed the tendency of both the cost and staff-time changes. For the costs, 54% of simulations estimated a non-significant median cost difference of -£33 (IQR: -£319 to £282) for Dilapan-S versus Propess. For the required midwife time, the difference was higher, with a median of −160 (IQR: −277 to −24) minutes of required midwife time with Dilapan-S in comparison to Propess.

Discussion

Using Dilapan-S instead of Propess was cost-neutral. A maternal decision to prefer Dilapan-S is therefore not expected to affect hospital budgets, given the presented model and setting. In the scenario analysis where waiting times before CRA insertion and amniotomy were set to zero, cost neutrality was maintained; as expected, removing waiting times did decrease total birth costs.

Regarding staff workload, the model predicted 147 fewer minutes for the midwife when using Dilapan-S in comparison to Propess. Key reasons for this time reduction are the minimal requirement of fetal monitoring after insertion of Dilapan-S due to the limited risk of hyperstimulation and a reduced need for prescription-only intravenous opioids during the cervical-ripening phase [14]. Although there was an increased need for analgesics during labour with Dilapan-S compared to Propess [14], their administration during labour was not expected to increase total midwife time. A further difference is that Propess requires repeated fetal monitoring every-six hours after insertion, whereas Dilapan-S can remain *in situ* without additional monitoring for the ripening period. The added burden to a midwife of managing and scheduling the monitoring and analgesics prescription needs of several women simultaneously was not modelled and may further reduce the workload during the cervical-ripening phase when using Dilapan-S.

In the UK, cervical ripening is midwife driven and there is little need for an obstetrician during the early phase of cervical ripening in the absence of complications. Although the total reduction of time was only 11 min on average, this represents a substantial overall time reduction of 54% for the obstetrician.

Staffing shortages and a high burden on existing staff have been reported for the UK in general [7,8]. More specific to midwifery, long working hours were positively associated with burnout in a 2013 British study [21]. A recent government report considers safe staffing requirements across the national health service (NHS) an area requiring improvement, mentioning persistent gaps in all maternity professions and significant issues with minimum staffing levels not being met on a daily basis [8,9]. The potential reduction in staff workload when using Dilapan-S instead of Propess might be one step towards improving maternity care and staff welfare.

Although our model predicts an overall reduction in staff workload for Dilapan-S in comparison to Propess, the SOLVE trial reports a substantial increase in the requirement of oxytocin augmentation and amniotomy with Dilapan-S; women may need to wait for staff and resource availability before initiating contractions, adding to their time in hospital [14]. The increased use of oxytocin is in agreement with published data comparing other mechanical methods to prostaglandins [22–24]. Another potential reason for the increased time to birth with Dilapan-S may be due to initial training required for insertion. Author experience suggests that about one in ten administrations of Dilapan-S requires the support of an obstetrician during the learning phase. Afterwards, insertion of Dilapan-S is performed by an experienced midwife.

Costs presented here are in line with previous UK costing analyses. Compared to a 2009 cost evaluation by the National Institute for Health Research, birthing costs ranged from GBP 1,334 (GBP 1,843 in 2020 GBP) for an uncomplicated birth with spontaneous labour to GBP 3,633 (5019 in 2020 GBP) for an unplanned caesarean birth [16]. In a further evaluation of direct costs to the NHS, an average birth with IOL using Propess in 2012 was reported to cost between GBP 1,569 and GBP 2,534 [10]. In 2020 equivalence, this is GBP 1,963 to GBP 3,169. These costs are well aligned with model results, especially if waiting times are excluded (Table 3).

Limitations

The model results are theoretical and would need to be confirmed in a study using real-world data. Not all input parameters were available from published literature, therefore, the consensus of the clinical practice from the authors was required to fill data gaps, especially in the area of monitoring and staff-time requirements. The SOLVE trial included a high proportion (80.3%) of nulliparous women recruited largely within one region of the UK (West Midlands), therefore data may not be representative of the UK maternity population [14]. However, it is a large randomised controlled trial including 674 women and the use of a single, consistent dataset may reduce errors introduced by combining input parameters from several clinical trials.

Conclusion

Adopting Dilapan-S for cervical ripening in comparison to Propess may contribute to a reduction in staff workload due to lower monitoring requirements and reduced prescription of analgesics during cervical ripening without impacting total birth costs. Alongside evidence that clinical and safety outcomes for Dilapan-S are at least comparable to Propess, there is potential for Dilapan-S to be used as the standard mechanical method for cervical ripening and for a more widespread use.

Contribution to authorship

KW contributed in the conception, planning, and editing of the final manuscript. SZ contributed in the conception, planning, and editing of the final manuscript. RTT contributed in the planning, analysis, and writing of the manuscript. SS contributed in the planning, analysis, and writing of the manuscript. RS contributed in the conception, analysis, and writing of the manuscript. JGK contributed in the conception, planning, and editing of the final manuscript.

Details of ethics approval

This work only used data from published literature and no patient-data was collected. Therefore, dedicated ethics approval was not required.

Declaration of Competing Interest

KW has no conflicts of interest. JKG has received honoraria for consultancy for Femcare-Nikomed and Bayer and support for attending meetings and travel from Medicem technology s.r.o. SZ is the PI for a retrospective e-Registry fully funded by Medicem reporting on outcomes of women induced with Dilapan-S. SJS and RTT are employees and RS is the owner of Coreva Scientific GmbH & Co KG, which received consultancy fees from Medicem for performing, analysing, and communicating the work presented here.

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Appendix A. Supplementary data

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