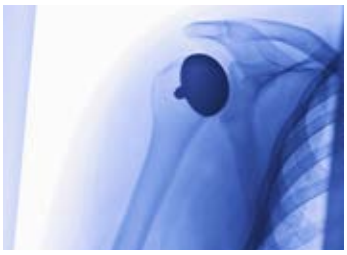
research

Unilateral or bilateral knee arthroplasty appropriate for unicompartmental osteoarthritis p 311

Induction of labour at 41 weeks associated with less adverse outcomes vs expectant management p 312



Early serious adverse events after shoulder replacement more common in elderly people p 314

ORIGINAL RESEARCH Systematic review and meta-analysis

Patient relevant outcomes of unicompartmental versus total knee replacement

Wilson HA, Middleton R, Abram S, et al

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Study question How do the outcomes after unicompartmental knee arthroplasty (UKA) or total knee arthroplasty (TKA) compare for patients with end stage medial compartment osteoarthritis?

Methods A systematic search of Medline, Embase, Cochrane Controlled Register of Trials (CENTRAL), and Clinical Trials.gov was made between 1 January 1997 and 31 December 2018. Studies that had more than 50 participants, were published in the past 20 years, and compared the outcomes of UKA with TKA in adult patients were included. Studies were separated into three study types (randomised controlled trials, studies from national joint registries and large national databases, and large cohort studies) for analysis, and separate analyses were carried out for domains of outcome identified as important by patients and clinicians.

Study answer and limitations 60 studies were included in the analysis. Both UKA and TKA appear to be viable options for the treatment of isolated unicompartmental osteoarthritis. Analysis of the three study groups showed significantly shorter hospital stays after UKA than after TKA (−1.20 days (95% confidence interval −1.67 to −0.73), −1.43 (−1.53 to −1.33), and −1.73 (−2.30 to −1.16), respectively). Overall, UKA had a lower risk of medical complications such as myocardial infarction, venous thromboembolic events and deep infections, lower mortality risk, and better functional outcomes. For several outcome domains, there was disagreement among the three study groups, and the results did not differ significantly in several analyses. Early reoperation for any reason was higher after TKA, but risk of revision surgery at five years was found to be higher after UKA in all three study groups (risk ratio 5.95 (1.29 to 27.59), 2.50 (1.77 to 3.54), and 3.13 (1.89 to 5.17), respectively). For each level of evidence analysed, there was a risk of bias, including sample size, lack of appropriate propensity matching, and selective outcome reporting. The amount of data available from randomised controlled trials was also limited.

What this study adds This study synthesises the available data comparing relevant outcome domains after UKA and TKA into a more accessible format to better inform patients and clinicians for shared decision making.

Funding, competing interests, and data sharing No funding was provided. No competing interests declared. The full dataset and all technical appendices are available from the corresponding author.
Systematic review registration PROSPERO CRD42018089972.

Optimising the management of late term pregnancies

ORIGINAL RESEARCH Multicentre, randomised non-inferiority trial

Induction of labour at 41 weeks versus expectant management until 42 weeks (INDEX)

Keulen JKJ, Bruinsma A, Kortekaas JC, et al

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Study question Is expectant management of labour until 42 weeks non-inferior to induction of labour at 41 weeks in low risk women with an uncomplicated pregnancy?

Methods This open label, randomised controlled non-inferiority trial was carried out in 123 primary care midwifery practices and 45 hospitals (secondary care) in the Netherlands. 1801 low risk women with an uncomplicated pregnancy were randomised to either induction at 41 weeks (n=900) or expectant management until 42 weeks with subsequent induction if necessary (n=901). Primary outcome was a composite of perinatal mortality and neonatal morbidity (Apgar score <7 at five minutes, arterial pH <7.05, meconium aspiration syndrome, plexus brachialis injury, intracranial haemorrhage, and admission to a neonatal intensive care unit (NICU)). Secondary outcomes included maternal outcomes and mode of delivery.

Study answer and limitations 15 women in the induction group (1.7%) and 28 in the expectant management group (3.1%) had a composite adverse perinatal outcome (absolute risk difference −1.4%, 95% confidence interval −2.9% to 0.0%; number needed to treat 69, 95% confidence interval 35 to 3059). The P value for non-inferiority was 0.22, indicating that it was not possible to exclude that expectant management leads to 2% or more adverse perinatal outcomes compared with induction. The incidence of

Main outcomes. Values are numbers (percentages) unless stated otherwise

Outcomes	Induction of labour (n=900)	Expectant management (n=901)	Relative risk (95% CI)	P value
Median (interquartile range) gestational age delivery (days)	287 (287-288)	289 (287-292)	−2.1 (−2.3 to −1.9)*	<0.001†
Induction of labour	640 (71.1)	237 (26.3)	2.70 (2.41 to 3.04)	<0.001
CAPO*	15 (1.7)	28 (3.1)	0.54 (0.29 to 1.00)	0.045†
CAPO with 5 min Apgar score <4 (instead of <7)	4 (0.4)	12 (1.3)	0.33 (0.11 to 1.03)	0.06†
Stillbirth (no neonatal deaths)	1 (0.1)	2 (0.2)	0.50 (0.05 to 5.51)	1.00†
Apgar score 5 mins post partum‡:				
<7	11 (1.2)	23 (2.6)	0.48 (0.23 to 0.98)	0.038
<4	0 (0.0)	3 (0.3)	NA	-
NICU admission	3 (0.3)	8 (0.9)	0.38 (0.10 to 1.41)	0.23†
(Secondary) caesarean section	97 (10.8)	97 (10.8)	1.00 (0.77 to 1.31)	0.99

CAPO=composite adverse perinatal outcome; NA=not applicable; NICU=neonatal intensive care unit.
*Defined as perinatal mortality, and/or a 5 minute Apgar score <7, and/or meconium aspiration syndrome, and/or plexus brachialis injury, and/or intracranial haemorrhage, and/or NICU admission.
†Fisher's exact test.
‡Apgar score of live births.

COMMENTARY Inconclusive evidence and high induction rates affect quality of care for women

A recent Cochrane systematic review,[2] which included 30 randomised trials and more than 12 000 women, found that a policy of induction at or beyond the expected date of birth (usually after 41 weeks) compared with expectant management was associated with fewer perinatal deaths, neonatal admissions to intensive care, and caesarean sections but more operative vaginal births. The review highlighted the need for more trials to examine the optimal timing of induction, and Keulen and colleagues should be congratulated on their paper (see above), reporting such a trial.[3]

Their results suggest that induction of labour at 41 weeks, compared with expectant management, is associated with a reduction in the risk of adverse perinatal outcome with no increase in caesarean section rates. Their interpretation should be viewed with caution, however, as the main contributor to the composite primary outcome is a standardised assessment of the newborn infant five minutes after birth (Apgar score), which is not closely associated with longer term neurological disability.[4] If the Apgar scores of less than 7 at five minutes are excluded, the remaining data suggest little to choose between these two management options.

The current debate around the timing of induction has been stimulated by the publication in of the 35/39 trial[5] from the UK in 2016, and ARRIVE (A Randomized Trial of Induction Versus Expectant Management) from the US in 2018.[6] The 35/39 trial suggested that for women older than 35 years, induction of labour at 39 weeks compared with expectant

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severe adverse outcomes—perinatal mortality (induction 1/900, expectant 2/901), Apgar score <4 at five minutes (induction 0/899, expectant 3/899), and NICU admission (induction 3/899, expectant 8/899)—was low. The rate of caesarean section did not differ between the groups (both 10.8%). Although randomisation was not stratified by parity, similar differences were observed between the groups. Not all eligible women were invited, and not all women who were asked participated, because of a preference for induction or expectant management.

What this study adds Induction of labour at 41 weeks resulted in less overall adverse perinatal outcome than expectant management until 42 weeks, although the absolute risk of severe adverse outcome (perinatal mortality, Apgar score <4 at five minutes, NICU admission) was low in both groups.

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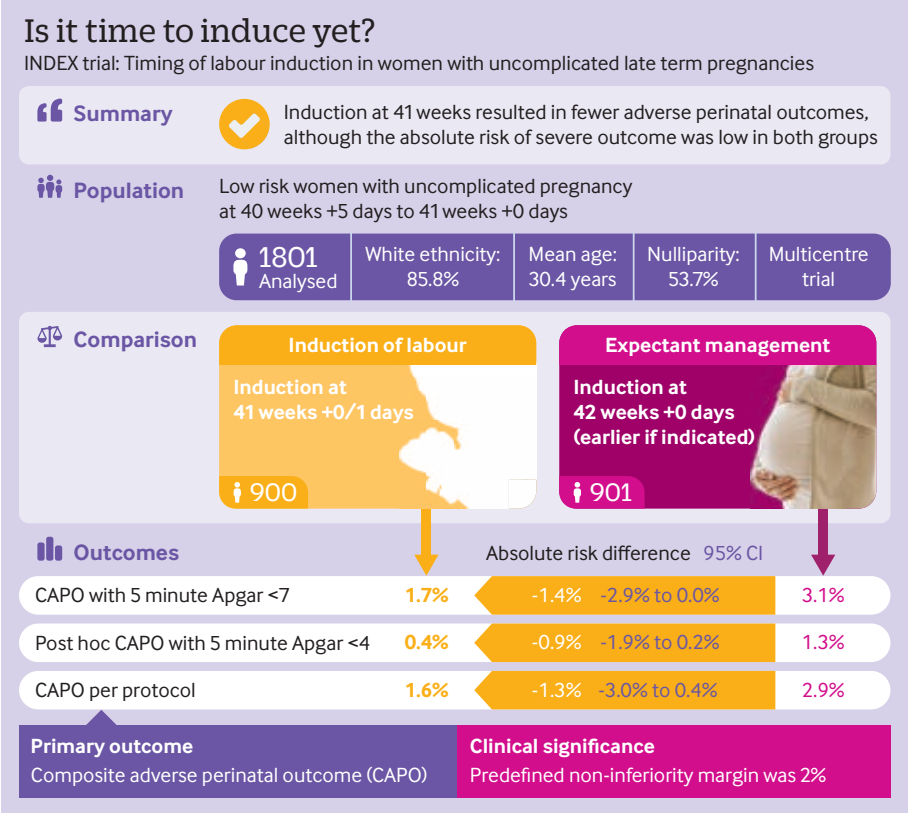
Study registration Netherlands Trial Register NTR343.



management had no effect on the rate of caesarean section or short term maternal or neonatal outcomes. The ARRIVE trial suggested that in low risk women having their first baby, induction after 39 weeks' gestation was associated with a reduction in caesarean section rates and no differences in neonatal outcomes.

Neither trial was sufficiently powered to assess perinatal mortality and neither addressed long term outcomes for the babies. However, discussion was provoked[7] by the large numbers of eligible women who declined to participate in both trials, and the same occurred in the trial by Keulen and colleagues: more than 6000 women had to be approached to achieve the recruitment target of 1800. This might indicate that those who did participate were different from the general population, and the authors highlight that this trial included mainly white women younger than 35 years. Meaningful involvement from the public in trial design (not reported in Keulen and colleagues' trial) might have improved recruitment rates, and future trials should ensure full patient and public partnership from the outset. These trials suggest that many women have a preference for either induction or watchful waiting. A recent systematic qualitative review of women's experiences of induction found that they did not feel involved in decision making and were unprepared for many aspects of the induction process, suggesting induction could have a negative impact on a woman's experience of childbirth.[8]

Excessive workloads in maternity units are causing widespread delays both in the initiation of induction and in care during the induction process

Variable rate

Induction rates vary between developing (4-12%) and developed countries (20-30%) and within individual countries.[9] The rate is also increasing over time—35% of nulliparous women are currently induced in the UK.[10] This substantial increase has resulted in serious challenges for service delivery that may also impact negatively on women's birth experience. Excessive workloads in maternity units are causing widespread delays both in the initiation of induction and in care during the induction process, sometimes with serious consequences.[8 11] Delays in induction cause anxiety and distress for women who have been told induction is indicated and that continuation of their pregnancy is associated with increased risks.

The results of this new trial are not sufficiently conclusive to change current practice, and we await with interest the results of the forthcoming SWEPIS trial, which may help resolve this question.[12] SWEPIS is a register based multicentre randomised controlled trial comparing induction at 41 weeks with expectant management that includes a consideration of parity, risk status, and women's experiences. The findings are expected later this year.

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Find the full version with references at http://dx.doi.org/10.1136/bmj.l681

ORIGINAL RESEARCH

Population based cohort study using hospital episode statistics for England

Serious adverse events and lifetime risk of reoperation after elective shoulder replacement

Craig RS, Lane JCE, Carr AJ, Furniss D, Collins GS, Rees JL

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Find this at: http://dx.doi.org/10.1136/bmj.l298

Study question What are the risks of serious adverse events, including the lifetime risk of revision surgery, for patients after elective shoulder replacement surgery for arthritis?

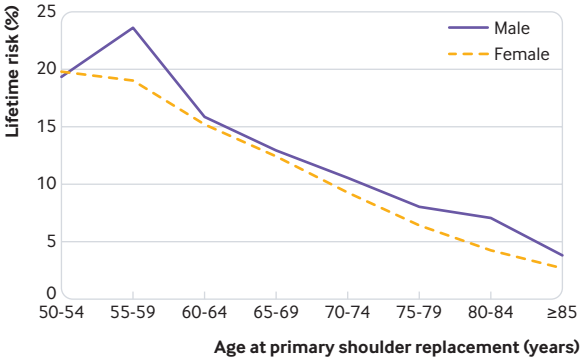
Methods Age and sex specific outcomes after 58 054 elective shoulder replacement procedures were analysed using data from hospital episode statistics for NHS England from 1998 to 2017. The lifetime risk of implant revision surgery was calculated using life tables and the current probability method. Rates were calculated at 30 and 90 days after surgery for death, pulmonary embolism, myocardial infarction, lower respiratory tract infection, acute kidney injury, urinary tract infection, and cerebrovascular events.

Study answer and limitations Adverse events were strongly associated with increasing age, comorbidity, and male sex. 1 in 5 (21.2%) men aged 85 years or older experienced a serious adverse event within 90 days, compared with 1 in 22 (4.6%) for the whole cohort. Lifetime risks of revision surgery ranged from 1 in 37 (2.7%) for women aged 85 years and older to 1 in 4 (23.6%) for men aged 55-59 years. At least half of this risk occurred within the first five years after surgery across all age groups. 1 in 22 (4.6%) participants experienced a serious adverse event within 90 days. Lifetime risk calculations were limited by the length of available follow-up and could represent an underestimate in younger patients.

What this study adds Early serious adverse events are much more common than previously found, particularly in elderly people. The lifetime risk of revision surgery after elective shoulder replacement is low in elderly people, but surprisingly high for adults aged less than 60 years. Revision risk is particularly high in the first five years after surgery.

Study registration ClinicalTrials.gov NCT03573765.

Funding, competing interests, and data sharing This research was supported by the National Institute for Health Research Oxford Biomedical Research Centre. No competing interests declared. No additional data are available. The supplementary material on bmj.com contains fully age and sex stratified risk tables to support discussions with patients.



Lifetime risk of implant revision after elective primary shoulder replacement, stratified by sex and age at time of primary procedure

No of patients undergoing surgery by age and sex

	50-54	55-59	60-64	65-69	70-74	75-79	80-84	≥85
Male	1013	1491	2254	3092	3217	2786	1484	636
Female	1076	1942	3642	6306	8952	9902	6814	3446

AUTHOR OPINION

Richard Craig and Jonathan Rees

Providing better evidence in orthopaedic surgery

Part of a clinician's duty of care is to provide patients with information on "the benefits, risks, burdens, and likelihood of success" when offering surgical treatments. The ease with which placebos can be used in medical randomised controlled trials (RCTs) has put physicians decades ahead of surgeons in providing treatments based on high level evidence. Providing such evidence in surgery has been far more challenging. Recently, however, funders, surgeons, trial methodologists, and ethicists have realised that not only can national multicentre surgical trials be successfully recruited to target, but that placebo surgical trials can also be designed and successfully delivered.

Our findings serve as a reminder that it is a major operation carrying real risks that patients and surgeons need to understand and accept

As such there is now a growing momentum, enthusiasm, and commitment within surgical communities—particularly in orthopaedic surgery, to address remaining evidence gaps. One ongoing uncertainty has been around the lack of high quality data on the use of different types of shoulder replacement surgery. While still considered the gold standard of evidence, RCTs in this context are underpowered to reliably detect differences in serious adverse events or longer term risks from revision surgery. It is the latter in particular that patients wish to have more information on, especially as the incidence of shoulder replacement surgery has risen dramatically and it has become the established treatment for painful end stage glenohumeral joint arthritis.

Our analysis of lifetime revision risk and serious adverse events provides information with sufficient clinical detail to be used in a meaningful way with patients of different sexes and age in the context of an individual's life expectancy. While shoulder replacement surgery might provide substantial benefit to many, our findings serve as a reminder that it is a major operation carrying real risks that patients and surgeons need to understand and accept.

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