Pregnancy in patients with implantable cardiac defibrillators

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Funding Sources / conflicts of interest

Dr Wong is supported by NHF post-doctoral scholarship.

Word count: 4141 words including references

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GERMAN ABSTRACT:

Die Zahl der Patienten im gebärfähigen Alter mit angeborener und angeborener Herzkrankheit, die implantierbare Herzdefibrillatoren (ICD) tragen, nimmt stetig zu. Die sichere und effektive Koordination der Schwangerschaft in dieser Hochrisikokohorte ist wichtig, um die Ergebnisse von Mutter und Fötus zu optimieren. Als Mitglieder des multidisziplinären Teams, das sich um schwangere Patienten mit Indikationen für ICD kümmert, sollten sich Kardiologen und Elektrophysiologen der Überlegungen und Nuancen bewusst sein, die mit der Behandlung dieser Patienten verbunden sind. Dieser Artikel befasst sich mit der Pathophysiologie von Arrhythmien, Überlegungen zur ICD-Implantation, neuartigen Techniken der minimalen Fluoroskopie, subkutanem ICD, vorgeburtlichem und Gerätemanagement während der Schwangerschaft und Entbindung.

GERMAN KEYWORDS:

Implantierbarer Herzdefibrillator, vererbtes Arrhythmie-Syndrom, Kardiomyopathie, Schwangerschaft, Schwangerschaftsvorsorge

ENGLISH ABSTRACT:

The number of patients of reproductive age with inherited and congenital heart disease carrying implantable cardiac defibrillators (ICD) is steadily increasing. Safely & effectively coordinating pregnancy in this high-risk cohort is important to optimise maternal-foetal outcomes. As members of the multidisciplinary team caring for pregnant patients with indications for ICD, cardiologists and electrophysiologists should be aware of the considerations and nuances involved in managing these patients. This article reviews the pathophysiology of arrhythmias, ICD implantation considerations, novel minimal fluoroscopy techniques, subcutaneous ICD, antenatal and device management during pregnancy and delivery.

ENGLISH KEYWORDS:

Implantable cardiac defibrillator, inherited arrhythmia syndrome, cardiomyopathy, pregnancy, antenatal care

ABBREVIATIONS:

ICD	Implantable cardiac defibrillator
DCM	Dilated cardiomyopathy
HCM	Hypertrophic cardiomyopathy
ARVC	Arrhythmogenic right ventricular cardiomyopathy
LQTS	Long QT syndrome
CPVT	Catecholaminergic polymorphic ventricular tachycardia
BrS	Brugada syndrome
VA	Ventricular arrhythmia
VT	Ventricular tachycardia
VF	Ventricular fibrillation
RV	Right ventricle

Introduction

Between 1-4% of pregnant women have cardiovascular disease representing the most frequent non-obstetric cause of maternal death accounting for 4.23 deaths per 100,000 live births [3]. Over the last three decades, implantable cardiac defibrillator (ICD) devices have been increasingly utilised in patients with inherited cardiovascular disorders and congenital heart disease. Consequently, there is a growing cohort of women of reproductive age living with ICDs requiring personalised multidisciplinary care and counselling when choosing to embark on pregnancy. This review aims to provide an overview of pregnancy-related physiology, epidemiology, outcomes and management considerations in patients with ICDs.

Pregnancy and ventricular arrhythmia

Cardiac conditions associated with ventricular arrhythmia in young female patients include structural heart disease, dilated cardiomyopathy (DCM), hypertrophic cardiomyopathy (HCM), arrhythmogenic cardiomyopathy (ACM), congenital heart disease and inherited arrhythmia syndromes such as long QT syndrome (LQTS), catecholaminergic polymorphic ventricular tachycardia (CPVT) and Brugada syndrome (BrS). A European registry study of three thousand pregnancies in females with structural heart disease found that ventricular arrhythmias occurred in 1.4% of pregnant women [13]. The presence of ventricular arrhythmia was associated with significantly higher incidence of heart failure (24%) and worse foetal outcomes including neonatal death (4.8%), pre-term birth (36%) and low birthweight (33%) compared with patients without ventricular arrhythmia.

Physiological changes

The exact mechanism of increased arrhythmia burden in pregnancy is not fully elucidated but thought to involve hemodynamic, hormonal and autonomic changes. Cardiac output and stroke volume increases by 30-50% and sympathetically mediated heart rate increases of 10-15% occur in the first trimester and peak at 34 weeks gestation. Systemic vascular resistance decreases in response to endogenous vasodilators [15]. Greater intra-thoracic impedance and thoracic fluid content have been reported utilising indices from longitudinal antenatal ICD monitoring [16]. The expansion in plasma volume and resultant atrial and ventricular hypertrophy may lead to stretch-associated early after depolarisations, shortened refractoriness, conduction slowing and spatiotemporal dispersion. Oestrogen has been shown to increase adrenergic receptor expression and sensitivity in cardiac myocytes during pregnancy [10]. Taken together, these physiological changes may facilitate the development and maintenance of re-entrant circuits in pregnancy.

Defibrillators in pregnancy

In pregnant patients with heart disease, approximately 3% have ICD implants [26]. Pregnant patients with unstable ventricular arrhythmia and at high risk of sudden cardiac death (SCD) should be considered for ICD implantation, according to current primary and secondary prevention of ventricular arrhythmia European Society of Cardiology (ESC) guidelines, similarly to non-pregnant patients [20]. Recent ESC guidelines for the management of cardiovascular diseases during pregnancy also recommend consideration of ICD implantation in at-risk patients prior to pregnancy [23]. Timing of implantation should thus form an important part of pre-pregnancy screening and counselling in such patients.

ICD Implantation

When indicated during pregnancy, ICD implantation can be performed safely, particularly beyond 8 weeks foetal gestation (Figure 1) [23]. Specific safety considerations include risks of foetal radiation exposure and foetal compromise in the context of maternal hemodynamic instability or device shock therapy. Maternal factors such as hypercoagulability and optimal gravid uterus positioning represent challenges, particularly when performing pericardiocentesis or resuscitation following a complication. Therefore, when performing procedures beyond 20 weeks gestation, left lateral displacement with a wedge placed underneath the patient may be helpful [12]. Procedural planning when the foetus is viable should also consider the availability of emergent delivery options following interdisciplinary consultation with obstetric and foetal medicine colleagues.

Foetal radiation exposure should be minimised particularly in the critical embryogenic period in early pregnancy during organ and neuronal development. Radiation-induced malformations typically occur at doses of 100 to 250mGy with periods of highest vulnerability of growth retardation 1-8 weeks, microcephaly 2-15 weeks and neurological impairment at 8-15 weeks of gestation [31]. An ‘as low as reasonably achievable’ principle for radiation exposure should be maintained [23] and a consensus safety threshold of below 50mGy has been shown to avoid adverse foetal-maternal outcomes [6]. Risks, benefits and informed consent should be clearly communicated to the patient with measures to minimise radiation use to optimise procedural safety and success. Radiation reduction manoeuvres include placing source distant and receiver close to the patient, low-dose fluoroscopy collimated to a small window of interest, anteroposterior projections, short fluoroscopy times, avoiding direct abdominal screening and utilising an experienced cardiologist/proceduralist [23]. Although abdominal shielding may lower direct foetal radiation exposure, its benefit is limited by scatter radiation. With advances in imaging techniques, guidelines advocate for the

use of adjuvant modalities during pregnancy including 3-dimensional electroanatomic mapping and echocardiography [23].

Minimal or fluoroscopy-free transvenous ICD implantations can be safely performed with access obtained via cephalic vein dissection or ultrasound-guided axillary vein puncture and lead-placement using transoesophageal echo [1] or electroanatomic mapping [9]. In a pilot study of 35 patients undergoing ICD implantation, the Ensite NavX™ (St Jude Medical) system was used to visualise defibrillator and atrial leads within geometry of the right atrium (RA), right ventricle (RV) and superior vena cava (SVC) created by a steerable catheter [9]. ICDs were successfully implanted in all cases, with a mean procedure time of 66 ± 26 minutes and fluoroscopy-free lead positioning achieved in 84% of cases. However, challenges of this approach include incomplete geometry and inaccurate representation of true proximal lead position based on navigational system interpolation of the defibrillator coils. Therefore judicious use of fluoroscopy must be balanced by procedural success and avoidance of complications.

Subcutaneous ICD

Subcutaneous ICD (S-ICD) implantation is an emerging technique in patients without pacing requirements and can be performed intramuscularly using a purely anatomical approach with minimal/zero fluoroscopy (figure 1). Current guidelines recommend the use of routine defibrillation threshold testing (DFT) for S-ICD insertion owing to a paucity of evidence [30]. Randomised studies have shown that although DFT for transvenous ICD implantation was well-tolerated, it was not associated with any significant improvement in shock efficacy or reduction in arrhythmic death [30]. Additionally, DFT complications may include myocardial injury, impairment of ventricular contractility, hypotension, thromboembolic

events and respiratory depression [30], which may threaten maternal-foetal outcomes. Therefore the role of an alternative method utilising imaging of the S-ICD implant position using a PRAETORIAN score may potentially obviate the need for DFT [22], and be particularly useful in at-risk cohorts such as pregnant women. The PRAETORIAN-DFT randomised study is currently evaluating S-ICD implantation with and without DFT [21]. It will also evaluate the non-inferiority of omitting DFT in patients with adequate device positioning guided by a novel scoring system. Utilising the PRAETORIAN score in pregnancy presents the challenge of requiring a PA and lateral chest radiograph to ensure minimal S-ICD lead coil sternal fat and sub-generator tissue is present – this has to be balanced against the DFT risk. However, with optimal implant technique avoiding sub-coil fat with tunnelling and an intermuscular posterior pocket one can ensure effective device placement with zero/minimal fluoroscopy.

Outcomes in pregnancy with ICD

Robust evidence on the outcomes of patients with ICDs during pregnancy is lacking. Data is limited to case reports [7, 32] and four retrospective studies [8, 18, 19, 26]. Study findings are summarised in table 1. Natale and colleagues first described the safety of ICDs in an early multi-center series of 44 pregnant women with 42 intra-abdominal and 2 pre-pectoral secondary prevention ICDs [19]. Subsequent studies have examined contemporary cohorts of pregnant patients with pre-pectoral transvenous ICD implantation observing variable rates of ICD-related complications but no clear adverse foetal outcomes [8, 18, 26].

Shock therapy during pregnancy

The impact of shocks on foetal outcomes has not been comprehensively studied. However, internal ICD cardioversion has generally been considered to be safe during pregnancy. Early animal and human work has suggested that the mammalian foetal heart is relatively insulated to low levels of unsynchronised electrical energy owing to a high fibrillation threshold [11]. In contrast, cases of external cardioversion requiring urgent delivery post cardioversion due to foetal distress have been described [5, 29]. Barnes et al reported a case of direct current (DC) 50J cardioversion at 28 weeks gestation leading to acute foetal bradycardia and a tightly contracted uterus found at emergent caesarean section [5]. Foetal bradycardia and respiratory depression rapidly resolved within minutes of delivery indicative of shock-related adverse consequences rather than anti-arrhythmic administration. The authors postulated that despite the uterus not being within the transthoracic DC shock vector, amniotic fluid and uterine muscle are excellent conductors of electricity and thus an anteroapical approach and enlarged uterus may have accounted for foetal involvement.

Locally directed internal defibrillation at lower energy levels would be expected to carry a lower risk of electrical shunting to the foetal heart than external cardioversion. To date, studies of ICD shocks during pregnancy have largely demonstrated no definitive impact on foetal outcome. Natale et al found that there were no miscarriages in 11 pregnant patients who experienced ICD shocks [19]. Of these, 1 baby was stillborn but had no signs of foetal distress following the ICD shock. This study also showed that ventricular arrhythmia and shock burden did not increase during labour. Concordant with these findings, other reports have not observed miscarriages in patients experiencing ICD shocks in a woman with LQTS at 20 weeks gestation [26], following IVF at 10 weeks gestation [7] and in a patient non-adherent to beta blockers with CPVT at 26 weeks gestation [14].

A recent series of 12 pregnant patients by Boule et al [8] described a miscarriage 7 days following 2 ICD shocks at 4 weeks gestation. Whilst it was acknowledged this may be

explained by typical idiopathic miscarriage rates, the authors raised the possibility that ICD shocks at early gestational age may have contributed. Further systematic studies investigating the link between timing of ICD discharge as a determinant of foetal outcome are required.

ICD complications during pregnancy

Studies on complication rates of ICD during pregnancy are mixed, with some suggesting that ICD-related complications are not uncommon [19, 26] (Table 1). Morphological changes during pregnancy and muscular contractions experienced in labour have been considered as potential stressors on ICD systems. Natale et al found that device-related complications occurred in 18% of patients, including mild ICD pocket tenderness during abdominal expansion, abdominal generator migration and epicardial lead pericarditis, but no lead fractures were identified. In a study of 14 women (13 transvenous and 1 abdominal ICD systems) undergoing pregnancy, Schuler et al reported lead complications in two cases (5%) including an atrial lead fracture in the second trimester and defibrillator lead thrombus in a patient with undiagnosed factor V leiden requiring surgical intervention [26]. Two other transvenous ICD studies did not demonstrate any device or lead related complications during pregnancy [8, 18].

Inappropriate shocks do not appear to occur to a greater extent during pregnancy [18, 26] with only 1 woman experiencing shocks for atrial fibrillation and rapid ventricular rate [19] and another for t-wave oversensing [8]. Therefore, women should be appropriately counselled and screened for concomitant conditions which may predispose to complications such as thrombophilia.

Foetal outcomes

Foetal outcomes in patients with ICDs have not shown any significant differences to the general population. Studies have demonstrated a high rate of live births with 42 of 44 (95%) [19], 18 of 19 (95%) and 6 of 6 (100%) pregnancies [18] and no maternal deaths (Table 1). Boule et al reported a discrepant lower rate of live births in 14 of 20 pregnancies (70%) with results potentially skewed by one woman having 3 miscarriages and small study size [8]. Natale et al found that antiarrhythmics accounted for 2 babies (5%) being small for gestational age and 1 neonatal episode (5%) of transient hypoglycaemia in a mother on sotalol [19]. Similarly, potential beta-blocker related effects in another study of 20 births included intra-uterine growth restriction in 4 (20%), low birth weight in 3 (15%) and neonatal hypoglycaemia in 5 (20%) with no long-term adverse outcomes at 6 months [8]. Although there are potential foetal side effects, the importance of continuing cardiac medications are highlighted in reports of medication non-adherence contributing to sustained ventricular arrhythmia and ICD discharges during pregnancy [2, 26].

Management during pregnancy

Pregnant patients with ICDs are a high-risk pregnancy group who benefit from specialist multidisciplinary team support including obstetric nurses, maternal-foetal medicine specialists, anaesthetists, expert obstetricians, device physiologists and cardiologists with expertise in cardiomyopathy, congenital heart disease and inherited arrhythmia syndromes [25].

Antenatal ICD management

Device interrogations should be performed in the first and third trimesters, which fall within the recommendations of routine 6-monthly follow up interval for patients with ICDs (figure

1) [25]. This should occur in conjunction with close surveillance of underlying cardiac conditions as ventricular function may worsen during pregnancy thereby increasing VA risk [8]. Optimal programming of therapy algorithms should be individualised with consideration of the underlying cardiac pathology, indication (primary or secondary prevention), device type, ventricular arrhythmia characteristics, morphology discrimination and minimisation of RV pacing and inappropriate shocks [20, 30].

The importance of guideline-directed device therapy is highlighted in a recent study. It found that programming in accordance with guidelines only occurred in one third of ICDs in a primary prevention cohort and halved the incidence of avoidable shock [4]. Strict adherence to guidelines and reprogramming from 'out-of-the-box' settings [30] are therefore particularly important in high-risk groups such as pregnant patients with ICDs, to reduce the likelihood of adverse maternal-foetal outcomes. Specific conditions warrant programming modifications based on differential therapeutic responses to ventricular arrhythmia. In patients with ARVC, algorithms should emphasise anti-tachycardia pacing which has been shown to be highly successful in terminating even rapid ventricular tachycardia (VT) [17]. In contrast, as shocks for stable VT may be pro-arrhythmic in other inherited arrhythmia syndromes such as CPVT and long QT syndrome, these patients benefit from longer detection intervals and a single high rate ventricular fibrillation (VF) zone [24].

Delivery considerations

Pre-delivery planning should involve coordination between the aforementioned specialist multi-disciplinary team to ensure appropriate services are available. Patients should undergo close surveillance and delivery should ideally be performed in a tertiary level institution with access to the full suite of obstetric emergency surgical services and continuous cardiac

monitoring. Vaginal delivery is preferred in patients with cardiac disease [26]. However, studies have not systematically evaluated delivery methods in patients with ICDs. From the available data, modalities of delivery have ranged from 69% vaginal delivery [26] to 100% (6 of 6) via caesarean section [18] with no significant reported differences on ICD functioning, maternal events or foetal outcomes.

For vaginal delivery, studies have programmed ICDs in full therapy mode and no peri-partum inappropriate shocks have been reported (figure 1) [19, 26]. However, deactivating shocks in certain patients may be considered during labour. This includes patients with subcutaneous ICDs given theoretical concerns of inappropriate shock from oversensing uterine contractions and requires further evaluation but switching the device off with back up external defibrillation is prudent [27]. Device management during operative deliveries should observe perioperative device guidelines individualised for each patient [28]. ICDs for caesarean section should be programmed to 'monitor only' (safe mode) to avoid electromagnetic interference (EMI) problems from sources such as diathermy and therapies re-enabled immediately postoperatively. Bipolar diathermy at short low energy bursts should be utilised for haemostasis to reduce likelihood of EMI and if monopolar diathermy is necessary, diathermy and grounding cables should be remote from the ICD.

Clinical magnets should be available on the labour ward and operating theatre to suspend anti-tachycardia detection in the setting of inappropriate shocks or emergency surgical procedures where programming is not available. When applied, magnets should be securely attached to minimise inadvertent movement and have the advantage of prompt restoration of ICD therapies upon removal. While anti-tachycardia therapies are disabled, patients are at risk of potentially fatal arrhythmia and should be carefully monitored perioperatively and have external defibrillator pads positioned antero-posteriorly ≥10-15cm away from the generator. Clinicians involved in delivery should also be made aware that magnet application

to ICDs does not alter bradypacing functionality and reprogramming is needed to facilitate asynchronous pacing in pacemaker-dependent high EMI risk patients.

Postpartum management should include ICD interrogation and reprogramming to baseline settings and ongoing surveillance of cardiac status.

Conclusion

Pregnancy in patients with ICDs represents a small but increasingly encountered clinical situation in a high-risk population. ICDs can be safely implanted during pregnancy and the presence of an ICD does not appear to be associated with greater adverse outcomes during pregnancy compared with the general population. Appropriate patient counselling, surveillance, planning and screening to reduce device or lead-related complications is crucial. Care should be provided in a specialist multidisciplinary antenatal team environment. Further prospective study is required to inform the optimal, evidence-based, pregnancy-related care of patients with ICDs.

Figure 1. Summary of device considerations during pregnancy

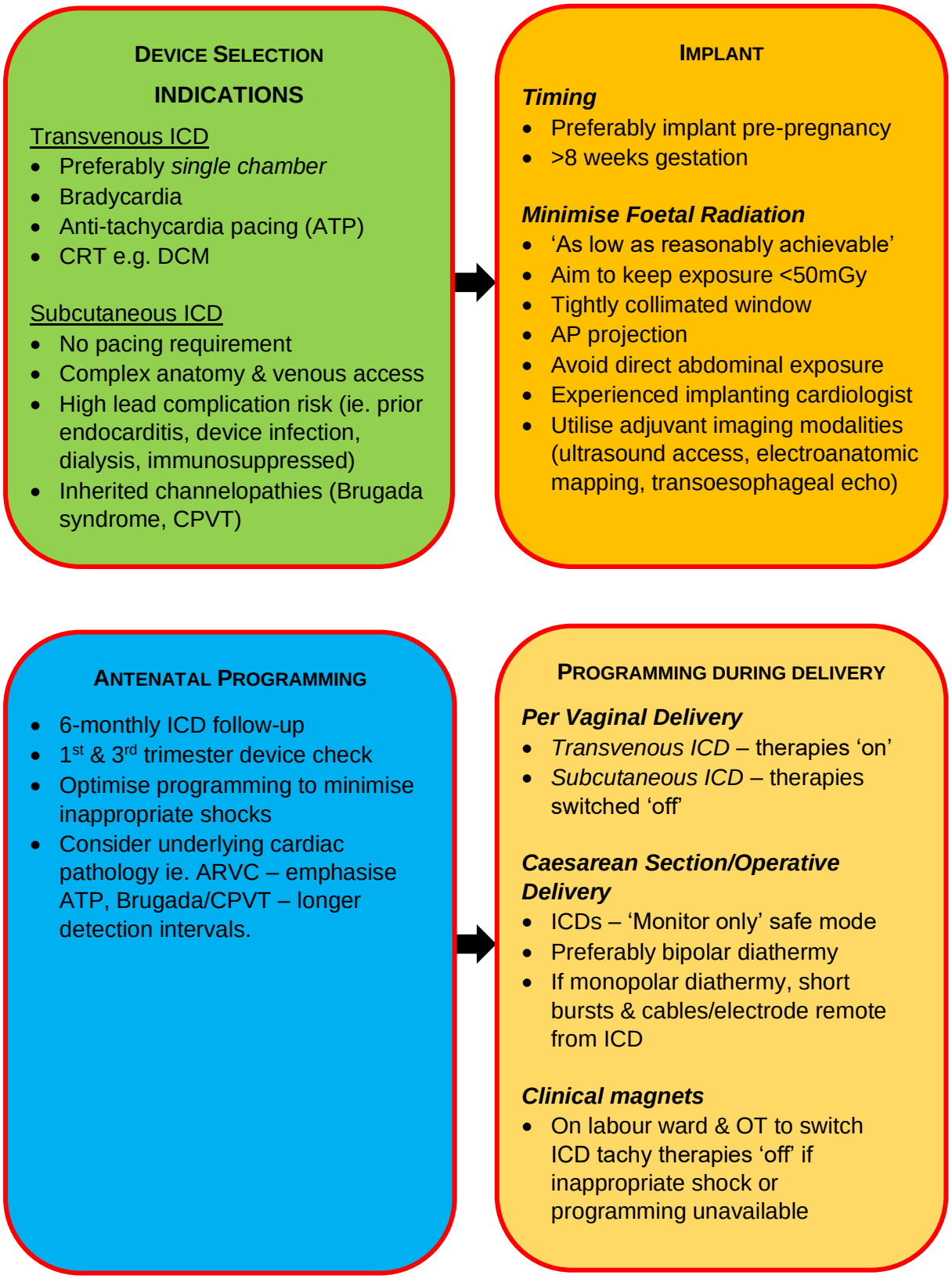

TABLE 1. Studies of outcomes of pregnancy in patients with implantable cardiac defibrillators (ICD).

	Year	Number of patients	Number of pregnancies	Mean Age (range)	Cardiac Disease N (%)	Primary prevention N (%)	Device Complications	PV Delivery N (%)	Live Births N (%)	Number of patients with ICD shocks N (%)	Adverse Foetal Outcomes in patients with shock N (%)
Natale et al	1997	44	51	30 (14-36)	IVF 17 (39) LQTS 13 (30) DCM 8 (18) CHD 3 (7)	0(0)	ICD site pain; Generator migration; Pericarditis (epicardial lead)	37 (84)	47 (92)	11 (25)	Stillborn 1 (9)
Schuler et al	2012	14	19	33 (22-42)	HCM 7 (50) LQTS 3 (21) CHD 1 (7) IVF 1 (7)	9 (64)	Surgery for ICD lead thrombus; Atrial lead fracture	12 (71)	18 (95)	1 (7)	Nil
Miyoshi et al	2013	6	6	28 (25-33)	LQTS 2 (33) DCM 2 (33) CHD 1 (17)	0 (0)	Nil	0 (0)	6 (100)	0 (0)	Nil
Boule et al	2014	12	20	28 (21-38)	CHD 3 (25) IVF 3 (25) HCM 2 (17) ARVC 2 (17) LQTS 1 (9)	3 (25)	Nil	6 (43)	14 (70)	2 (12)	Miscarriage 1 (5)

Abbreviations: LQTS – long QT syndrome; IVF – idiopathic ventricular fibrillation; DCM – dilated cardiomyopathy; HCM – hypertrophic cardiomyopathy; CHD – Congenital heart disease; ARVC – arrhythmogenic right ventricular cardiomyopathy; PV – per vaginal

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