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Pregnancy and neonatal outcomes of assisted pregnancies in a low-middle income country in South Asia

Sachith Mettananda^{1,2,3*}, Himali Herath^{3,4}, Ranod Madushith¹, Tiran Dias^{2,5}, Rasika Herath^{2,5}, Sampatha Goonewardena^{3,6}, Dhammica Rowel⁷, Abner Elkan Daniel⁷ and Susie Perera^{3,8}

Abstract

Background Assisted reproductive techniques are increasingly used to achieve fertility in developing countries in South Asia. However, the data on the outcome of assisted pregnancies are sparse. This study aims to evaluate the pregnancy, delivery and neonatal outcomes and complications of assisted pregnancies in Sri Lanka, a low-middle-income country in South Asia.

Methods We performed a secondary analysis of the data of the island-wide multi-centre Sri Lanka Birth Weight Study, which recruited all live-born newborns in 13 hospitals covering 20% of all births in the country from 01 August to 30 September 2023. Data on socio-demographic background, type of conception, pre-pregnancy medical, obstetric and delivery complications and immediate neonatal outcomes were collected by interviewing mothers and perusing patient records. Maternal age-, multiple births- and prematurity-adjusted odds ratios were determined by logistic regression analysis.

Results Of the 8992 pregnancies, 8900 (99.0%) were spontaneous conceptions. The assisted pregnancy rate was 1.0%, with 52 intra-uterine insemination and 40 in-vitro fertilisation pregnancies. The mean ages of mothers who had intra-uterine insemination (31.2 years) or in-vitro fertilisation (38.7 years) were significantly ($p < 0.001$) higher than the mothers who had spontaneous conceptions (28.6 years). Pregestational diabetes ($p = 0.003$) and hypothyroidism ($p < 0.001$) were significantly higher in the assisted pregnancy group compared to the spontaneous conceptions. Regarding pregnancy complications, gestational diabetes ($p = 0.001$) was higher in in-vitro fertilisation pregnancies and urinary tract infection ($p < 0.001$) was higher in intra-uterine insemination pregnancies. The multiple births (6.4% vs. 1.2%, $p < 0.001$) and caesarean section (77.2% vs. 41.8%, $p < 0.001$) rates were significantly higher among the assisted pregnancy group compared to spontaneous conceptions. Neonates born following assisted pregnancies were significantly more likely to be premature ($p < 0.001$), low birth weight ($p < 0.05$), admitted to neonatal intensive care units ($p < 0.001$) and die within the first day of life ($p < 0.05$) compared babies born following spontaneous conceptions.

*Correspondence:
Sachith Mettananda
sachith.mettananda@kln.ac.lk

Full list of author information is available at the end of the article



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Conclusions The assisted pregnancy rate in this study was 1%, and assisted pregnancies were more common among women with pregestational diabetes and hypothyroidism. Gestational diabetes and urinary tract infections were more frequent in assisted pregnancies. Neonates born following assisted pregnancies reported significant morbidity and mortality compared to spontaneous conceptions.

Keywords Assisted pregnancy, Assisted reproductive technology, *In-vitro* fertilisation, Intra-uterine insemination, Pregnancy outcome, Neonatal outcome

Introduction

Assisted pregnancies are pregnancies achieved through a diverse group of treatments and procedures known as Assisted Reproductive Technologies (ART) [1]. It is estimated that up to 10% of couples who embark on treatment for subfertility require the support of ART [2]. The most common forms of assisted pregnancies include intra-uterine insemination (IUI) and in-vitro fertilisation (IVF), which is mainly done by intracytoplasmic sperm injection (ICSI). According to the International Committee for Monitoring ART world report, the utilization of assisted pregnancy methods has increased over time. In 2016, it is estimated that over 900,000 infants were born following approximately 3.9 million assisted pregnancy treatment cycles [3].

The trends of ART have changed over the years in parallel to the advancements in the field. These advancements have focused on reducing multiple pregnancies and favouring single embryo transfer. Although assisted pregnancy methods have been increasingly utilized in high-income countries, their use in low- and middle-income countries is limited due to lack of expertise, knowledge, infrastructure and research [3]. Similarly, data on the rates of assisted pregnancies and the issues related to pregnancies achieved by ART in low- and middle-income countries are lacking.

A number of research performed in resource-rich countries have evaluated the problems and outcomes of assisted pregnancies. These studies have reported adverse pregnancy and neonatal outcomes following assisted pregnancies, which were traditionally attributed to the increased rate of multiple pregnancies following ART [4, 5]. Furthermore, there is some evidence that the rates of adverse pregnancy and neonatal outcomes following ART are higher even among singleton pregnancies [6].

Although ART is increasingly used to achieve fertility in developing countries in South Asia, the data on the outcome of these pregnancies are sparse. This is compounded by the stigma and negative attitude towards assisted pregnancies in these regions, leading to poor reporting [7, 8]. Therefore, in this island-wide multicentre cross-sectional study, we aim to evaluate the pregnancy, delivery and neonatal outcomes and complications of assisted pregnancies in Sri Lanka, a low-middle-income country in South Asia.

Methods

Sri Lanka is an island country in South Asia, with a per capita income of US\$ 3474. Major ethnicities include Sinhala, Sri Lankan Tamil, Indian Tamil and Muslim. Both male and female literacy rates are over 90% and most Sri Lankans study at least up to secondary education (Ordinary) level.

We performed a secondary analysis of data from the Sri Lanka Birth Weight Study. This study was an island-wide prospective multicentre study conducted from 01 August to 30 September 2023 in 13 hospitals representing all nine provinces and all tiers of hospitals (teaching, provincial general, district general and base hospitals) in Sri Lanka [9]. It covered 20% of all births in the country during the study period. Although the hospitals were in major cities, the service provision area covered urban, semi-urban and rural areas. Over 99% of births in Sri Lanka are institutional deliveries happening in hospitals. All teaching, provincial general, district general or base hospitals have level 2 or 3 neonatal intensive care units.

All live newborns born during the study period in selected hospitals were prospectively recruited for the study. Data were collected using an interviewer-administered questionnaire by interviewing mothers and perusing patient records by trained research assistants. The questionnaire contained questions on socio-demographic background, type of conception (i.e., spontaneous conception, IUI or IVF [all IVFs in Sri Lanka are ICSI]), pre-pregnancy medical complications, obstetric complications, delivery details, details of resuscitation at birth (defined as requiring inflation breaths or cardiac compressions) and immediate neonatal outcomes.

Data were analysed using IBM SPSS Statistics 29.0. Frequencies, percentages, means, and standard deviations were used to present descriptive statistics. The Independent sample t-test was used to compare means of continuous variables, and the χ^2 test was used to determine associations between categorical variables. When analysing maternal medical and obstetric complications, binary logistic regression was used to determine the odds ratios adjusted to maternal age and multiple births. Odds ratios of neonatal complications were adjusted to the prematurity and multiple births.

Ethical clearance was obtained from the Ethics Review Committee of the Sri Lanka College of Paediatricians (Ref. SLCP/ERC/2023/09). Informed consent was

obtained from all study participants before recruitment. Administrative approval was obtained from the Director General of Health Services and Directors of participating hospitals.

Results

A total of 8992 pregnancies were included, of which 8900 (99.0%) were spontaneous conceptions. The assisted pregnancy rate of the study population was 1.0% ($n = 92$). Fifty-two (0.6%) pregnancies were following IUI, and 40 (0.4%) pregnancies were following IVF.

Table 1 Socio-demographic characteristics of the study population

Characteristic	Spontaneous conception (<i>N</i> = 8900)	Assisted pregnancy (IUI and IVF) (<i>N</i> = 92)	IUI pregnancy (<i>N</i> = 52)	IVF pregnancy (<i>N</i> = 40)	All Pregnancies (<i>N</i> = 8992)
Maternal age					
=<19 years	388 (4.4%)	0	0	0	388 (4.3%)
20–35 years	7485 (84.1%)	51 (55.4%)	41 (78.9%)	10 (25.0%)	7536 (83.9%)
> 35 years	1023 (11.6%)	41 (44.5%)	11 (21.1%)	30 (75.0%)	1064 (11.8%)
Ethnicity					
Sinhala	4793 (53.9%)	46 (50.0%)	27 (51.9%)	19 (47.5%)	4839 (53.8%)
Sri Lankan Tamil	1821 (20.5%)	36 (39.1%)	19 (36.5%)	17 (42.5%)	1857 (20.7%)
Indian Tamil	670 (7.5%)	3 (3.3%)	2 (3.8%)	1 (2.5%)	673 (7.5%)
Muslim	1607 (18.1%)	7 (7.6%)	4 (7.7%)	3 (7.5%)	1614 (17.9%)
Other	9 (0.1%)	0	0	0	9 (0.1%)
Marital status					
Unmarried	98 (1.1%)	0	0	0	98 (1.1%)
Married	8779 (98.7%)	92 (100%)	52 (100%)	40 (100%)	8871 (98.7%)
Divorced	14 (0.2%)	0	0	0	14 (0.2%)
Widowed	8 (0.1%)	0	0	0	8 (0.1%)
Mother's occupation					
Housewife	6988 (78.7%)	55 (59.8%)	30 (57.7%)	25 (62.5%)	7043 (78.5%)
Employed	1893 (21.3%)	37 (40.2%)	22 (42.3%)	15 (37.5%)	1930 (21.5%)
Father's occupation					
Unemployed	39 (0.4%)	0	0	0	39 (0.4%)
Unskilled (e.g., labourer)	1705 (19.3%)	12 (13.2%)	8 (15.7%)	4 (10.0%)	1717 (19.3%)
Skilled (e.g., carpenter, driver, mason)	3789 (43.0%)	31 (34.1%)	18 (35.3%)	13 (32.5%)	3820 (42.9%)
Professional (e.g., doctor, lawyer, teacher, nurse)	1810 (20.5%)	29 (31.9%)	14 (27.5%)	15 (37.5%)	1839 (20.6%)
Business/Self-employed	1478 (16.8%)	19 (20.9%)	11 (21.6%)	8 (20.0%)	1497 (16.8%)
Mother's education level					
No Schooling	22 (0.2%)	0	0	0	22 (0.2%)
Primary (Grade 5)	657 (7.4%)	1 (1.1%)	0	1 (2.5%)	658 (7.3%)
Ordinary level (Grade 11)	4351 (48.9%)	34 (37.0%)	19 (36.5%)	15 (37.5%)	4385 (48.8%)
Advanced level (Grade 13)	2810 (31.6%)	33 (35.9%)	18 (34.6%)	15 (37.5%)	2843 (31.6%)
Higher education (Diploma or degree)	1055 (11.9%)	24 (26.0%)	15 (28.9%)	9 (22.5%)	1079 (12.0%)
Father's education level					
No Schooling	24 (0.3%)	0	0	0	24 (0.3%)
Primary (Grade 5)	828 (9.4%)	1 (1.1%)	1 (2.0%)	0	829 (9.3%)
Ordinary level (Grade 11)	4752 (53.7%)	38 (41.8%)	20 (39.2%)	18 (45.0%)	4790 (53.6%)
Advanced level (Grade 13)	2535 (28.7%)	36 (39.6%)	22 (43.1%)	14 (35.0%)	2571 (28.8%)
Higher education (Diploma or degree)	702 (7.9%)	16 (17.6%)	8 (15.7%)	8 (20.0)	718 (8.0%)
Monthly family income (LKR)					
≤ 25,000	720 (8.4%)	4 (4.5)	3 (6.1%)	1 (2.6%)	724 (8.3%)
25,001–50,000	4487 (51.9%)	24 (27.3%)	14 (28.6%)	10 (25.6%)	4511 (51.6%)
50,001–100,000	2657 (30.7%)	43 (48.9%)	19 (38.8%)	24 (61.5%)	2700 (30.9%)
> 100,000	783 (9.0%)	17 (19.3%)	13 (26.5%)	4 (10.3%)	800 (9.1%)

Socio-demographic characteristics of the study population

A majority of mothers in the study population were Sinhala (53.8%) and housewives (78.5%) (Table 1). Most fathers were in skilled employment (42.9%), while 20.6% worked as professionals. Regarding education level, 43.6% of mothers and 36.8% of fathers were educated beyond the Ordinary level. The monthly income of most families (51.6%) ranged between LKR 25,001–50,000.

The mean ($\pm$ SD) age of mothers who had IUI (31.2 ± 4.5 vs. 28.6 ± 5.4 , $p < 0.001$) or IVF (38.7 ± 5.7 vs. 28.6 ± 5.4 , $p < 0.001$) were significantly higher than the mothers who had spontaneous conceptions. Assisted pregnancies were significantly more frequent in higher socioeconomic groups (Table 2). A significantly higher proportion of mothers in the IUI group were employed compared to the spontaneous conceptions (42.3% vs. 21.3%, $p < 0.01$). A higher proportion of fathers in the IVF group were in professional occupations than in the spontaneous conception group (37.5% vs. 20.5%, $p < 0.01$). A significantly higher proportion of mothers (62.0 vs. 43.5%, $p < 0.001$) and fathers (57.1% vs. 36.6%, $p < 0.001$) in the assisted pregnancy group were educated up to Advanced level or higher compared to the spontaneous conception

group. Similarly, a higher proportion of families in the IUI (65.7%) and IVF (71.8%) groups had family income above LKR 50,000 compared to spontaneous conceptions (39.8%, $p < 0.001$).

Maternal medical complications of assisted pregnancies

Pregestational diabetes mellitus ($p < 0.05$) and hypothyroidism ($p < 0.001$) were significantly higher in the assisted pregnancy and IUI pregnancy groups compared to spontaneous conceptions (Table 3). The prevalence of chronic hypertension was significantly higher in the IVF group ($p < 0.05$).

Obstetric complications following assisted pregnancies

The prevalences of gestational diabetes ($p < 0.01$) and urinary tract infection ($p < 0.05$) were significantly higher among mothers who had assisted pregnancies compared to spontaneous conceptions (Table 4). When considering IUI and IVF separately, gestational diabetes was higher in IVF pregnancies ($p < 0.01$), and urinary tract infections were higher in IUI pregnancies ($p < 0.001$), respectively. The incidences of placental abnormalities like placenta previa and placental abruption were not significantly

Table 2 Association between assisted pregnancy methods and socio-demographic characteristics

Characteristic	Spontaneous conception (N = 8900)	Assisted pregnancy (IUI and IVF) (N = 92)		IUI pregnancy (N = 52)		IVF pregnancy (N = 40)	
	Number (%) with the characteristic	Number (%) with the characteristic	p-value compared to spontaneous conception*	Number (%) with the characteristic	p-value compared to spontaneous conception*	Number (%) with the characteristic	p-value compared to spontaneous conception*
Mother's employment status							
Housewife	6988 (78.7%)	55 (59.8%)	< 0.001	30 (57.7%)	< 0.001	25 (62.5%)	0.013
Working mother	1893 (21.3%)	37 (40.2%)		22 (42.3%)		15 (37.5%)	
Father's occupation							
Non-professional	7011 (79.5%)	62 (68.1%)	0.008	37 (72.5%)	0.222	25 (62.5%)	0.008
Professional	1810 (20.5%)	29 (31.9%)		14 (27.5%)		15 (37.5%)	
Mother's education level							
Ordinary level or lower	5030 (56.5%)	35 (38.0%)	< 0.001	19 (36.5%)	0.004	16 (40.0%)	0.035
Advanced level or higher	3865 (43.5%)	57 (62.0%)		33 (63.5%)		24 (60.0%)	
Father's education level							
Ordinary level or lower	5604 (63.4%)	39 (42.9%)	< 0.001	21 (41.2%)	0.001	18 (45.0%)	0.016
Advanced level or higher	3237 (36.6%)	52 (57.1%)		30 (58.8%)		22 (55.0%)	
Monthly family income (LKR)							
$\leq$ 50,000	5207 (60.2%)	28 (31.8%)	< 0.001	17 (34.7%)	< 0.001	11 (28.2%)	< 0.001
> 50,000	3440 (39.8%)	60 (68.2%)		32 (65.3%)		28 (71.8%)	

* p-value by χ^2 test

Table 3 Maternal medical complications in assisted pregnancy methods

Maternal medical complication	Assisted pregnancy (IUI and IVF) (N = 92)		IUI pregnancy (N = 52)		IVF pregnancy (N = 40)	
	Spontaneous conception (N = 8900)	Number (%) with the complication	AOR, 95%CI and p-value compared to spontaneous conception *	Number (%) with the complication	AOR, 95%CI and p-value compared to spontaneous conception *	Number (%) with the complication
Pregestational diabetes mellitus	197 (2.2%)	10 (10.9%)	AOR: 2.83, CI: 1.41–5.67 p = 0.003	5 (9.6%)	AOR: 3.42, CI: 1.32–8.86 p = 0.011	5 (12.5%)
Chronic hypertension	101 (1.1%)	5 (5.4%)	AOR: 2.52, CI: 0.97–6.56 p = 0.058	1 (1.9%)	AOR: 1.22, CI: 0.16–8.99 p = 0.849	4 (10.0%)
Hypothyroidism	276 (3.1%)	14 (15.2%)	AOR: 3.78, CI: 2.06–6.91 p < 0.001	9 (17.3%)	AOR: 5.47, CI: 2.61–11.43 p < 0.001	5 (12.5%)
Asthma	619 (7.0%)	5 (5.4%)	AOR: 0.63, CI: 0.25–1.58 p = 0.325	4 (7.7%)	AOR: 1.02, CI: 0.37–2.84 p = 0.974	1 (2.5%)
Epilepsy	78 (0.9%)	2 (2.2%)	AOR: 3.22, CI: 0.76–13.7 p = 0.114	1 (1.9%)	AOR: 2.40, CI: 0.33–17.69 p = 0.389	1 (2.5%)
Anaemia (pre-pregnancy)	1931 (22.2%)	14 (15.4%)	AOR: 0.60, CI: 0.34–1.08 p = 0.089	6 (11.5%)	AOR: 0.46, CI: 0.19–1.07 p = 0.070	8 (20.5%)

* AOR- Odds ratios adjusted for maternal age and multiple births in logistic regression; CI- 95% Confidence interval.

different between assisted pregnancy and spontaneous conception groups ($p > 0.05$).

Delivery characteristics

Multiple births were higher following assisted pregnancy methods ($p < 0.001$) (Table 5). 1/52 (1.9%) IUI pregnancies and 2/40 (5.0%) IVF pregnancies were twin pregnancies compared to 102/8900 (1.1%) spontaneous conceptions. Similarly, 1/52 (1.9%) IUI pregnancies and 3/40 (7.5%) IVF pregnancies had triplets compared to 1/8900 (0.0001%) spontaneous conceptions. A significantly higher proportion of assisted pregnancies were confined by elective ($p < 0.05$) or emergency ($p < 0.05$) caesarean section compared to spontaneous pregnancies.

Neonatal outcomes

A total of 9115 neonates were born alive in the 8992 pregnancies included in the study. Fifty-five neonates were born following IUI, and 46 neonates were born following IVF pregnancies. Neonates born following assisted pregnancies reported a number of adverse outcomes (Table 6). The incidence of prematurity ($p < 0.001$) and low birth weight ($p < 0.05$) were higher in assisted pregnancies. However, small for gestational age did not show a significant association with the assisted pregnancy methods. A significantly higher proportion of babies born following assisted pregnancies were admitted to the neonatal intensive care units ($p < 0.001$) and died within the first day of life ($p < 0.05$), even after adjusting for prematurity and multiple births. Details of complications in assisted pregnancy methods are given in Supplemental Tables 1 and 2.

Discussion

Here, we present the findings of a large island-wide multicentre study that evaluated the pregnancy, delivery, and neonatal outcomes of assisted pregnancies in Sri Lanka. Although the outcome of assisted pregnancies has been studied in developing countries, similar studies in low-middle-income countries, specifically in South Asia, are limited [3]. Ours is possibly the first study evaluating the outcome and complications of assisted pregnancies in Sri Lanka; hence, it provides valuable information on ART outcomes for health policymakers in South Asia.

The assisted pregnancy rate in our study was 1.0%, of which 0.6% were IUIs and 0.4% were IVF. This rate is significantly lower than the rates reported in developed countries [10]. IVFs in Sri Lanka currently use ICSI technology and, therefore, incur significant costs to the couples. The low assisted pregnancy rates reported in our study are likely due to the limitation of resources and the high cost associated with IVF [3, 7]. Our results revealed that pregestational diabetes mellitus and hypothyroidism are more common among the mothers who underwent

ART compared to the spontaneous conceptions, even after adjusting for maternal age. This could be due to the increased risk of subfertility among women with diabetes and hypothyroidism [11].

Regarding pregnancy complications, we found that the risk of gestational diabetes is higher among ART pregnancies, especially in IVF pregnancies, even after correcting for maternal age and multiple births. The reason for this increase is uncertain but could be due to the association of conditions that lead to subfertility through ovulation disorders and tubal blockage with the increased risk of gestational diabetes [12]. Similar findings of higher prevalence of gestational diabetes among ART groups have been reported in previous studies; however, these studies did not adjust the results to the maternal age [4, 13, 14].

Another complication seen in ART pregnancies was the higher rates of UTI among IUI pregnancies. As the UTI prevalence was not higher among IVF pregnancies, UTI is likely due to manipulations during the IUI procedure rather than a complication associated with the ART process, per se.

Another important observation of the study is the extremely high caesarean section rates (77%) in assisted pregnancies compared to spontaneous conceptions (42%). This was predominantly seen among IVF pregnancies, of which 95% were confined by caesarean section. This contrasts with the low caesarean section rates reported in developed countries. Although the studies done in the USA and Australia have revealed higher caesarean section rates among ART pregnancies in comparison to spontaneous conceptions, the reported rates are 45–50% [15, 16]. The very high caesarean section rate in Sri Lankan IVF pregnancies is probably due to the parental and medical professionals' anxiety and fear of losing the precious pregnancy. The extremely high cost of IVF (approximately USD 4000–5000 for a single cycle) compared to low average wages (per capita income of USD 3474) creates a significant social and economic burden on families if these pregnancies are lost [17].

The most significant finding of our study is the report of adverse neonatal outcomes of assisted pregnancies compared to spontaneous conceptions. The rates of prematurity and low birth weight were higher in all forms of assisted pregnancies, even after adjusting for multiple births. More importantly, a significantly higher proportion of neonates of assisted pregnancies were admitted to the neonatal intensive care units and died within the first day of life, even after adjusting for prematurity and multiple births. The reason for these adverse outcomes is uncertain and needs further research.

One important limitation of the study is that the study population did not include pregnancy losses. The Sri Lanka Birth weight study only recruited live-born infants;

Table 4 Obstetric complications following assisted pregnancy methods

Obstetric complication	Spontaneous pregnancy (N=8900)		Assisted pregnancy (IUI and IVF) (N=92)		IUI pregnancy (N=52)		IVF pregnancy (N=40)	
	Number (%) with the complication	Number (%) with the complication	Number (%) with the complication	AOR, 95%CI and p-value compared to spontaneous conception *	Number (%) with the complication	AOR, 95%CI and p-value compared to spontaneous conception *	Number (%) with the complication	AOR, 95%CI and p-value compared to spontaneous conception *
Pregnancy-induced hypertension	431 (4.8%)	9 (9.8%)	AOR:1.57, CI: 0.77–3.19 p=0.212	5 (9.6%)	AOR:1.81, CI: 0.71–4.60 p=0.211	4 (10.0%)	AOR:1.38, CI: 0.47–4.12 p=0.556	
Gestational diabetes	853 (9.6%)	21 (22.8%)	AOR:2.07, CI: 1.25–3.43 p=0.005	8 (15.4%)	AOR:1.47, CI: 0.69–3.14 p=0.323	13 (32.5%)	AOR:3.17, CI: 1.56–6.45 p=0.001	
Urinary tract infection	361 (4.1%)	8 (8.7%)	AOR:2.46, CI: 1.15–5.26 p=0.020	7 (13.5%)	AOR:3.92, CI: 1.75–8.78 p<0.001	1 (2.5%)	AOR:0.34, CI: 0.04–3.18 p=0.346	
Chorioamnionitis	32 (0.4%)	0	AOR:0.0, CI: 0.00 p=0.998	0	AOR:0.0, CI: 0.00 p=0.998	0	AOR:0.0, CI: 0.00 p=0.998	
Polyhydramnios	90 (1.0%)	2 (2.2%)	AOR:1.24, CI: 0.29–5.34 p=0.775	1 (1.9%)	AOR:1.54, CI: 0.21–11.37 p=0.670	1 (2.5%)	AOR=1.39, CI: 0.15–12.79 p=0.768	
Placenta previa	71 (0.8%)	1 (1.1%)	AOR: 1.37, CI: 0.18–10.34 p=0.76	0	AOR:0.0, CI: 0.00 p=0.997	1 (2.5%)	AOR: 1.06, CI: 0.11–10.33 p=0.962	
Placental abruption	40 (0.4%)	1 (1.1%)	AOR: 1.71, CI: 0.22–13.38 p=0.609	0	AOR: 0.0, CI: 0.00 p=0.998	1 (2.5%)	AOR: 5.22, CI: 0.60-45.37 p=0.134	
Anaemia (at delivery)	1695 (19.3%)	15 (16.7%)	AOR: 0.79, CI: 0.45–1.39 p=0.422	9 (18.0%)	AOR: 0.90, CI: 0.44–1.87 p=0.784	6 (15.0%)	AOR: 0.64, CI: 0.26–1.59 p=0.334	

* AOR- Odds ratios adjusted for maternal age and multiple births in logistic regression; CI- 95% Confidence interval.

Table 5 Delivery characteristics of pregnancies following assisted pregnancy methods

Delivery characteristic	Spontaneous conception (N = 8900)	Assisted pregnancy (IUI and IVF) (N = 92)		IUI pregnancy (N = 52)		IVF pregnancy (N = 40)	
	Number (%) with the feature	Number (%) with the complication	p-value compared to spontaneous conception	Number (%) with the complication	p-value compared to spontaneous conception	Number (%) with the complication	p-value compared to spontaneous conception
Singleton or multiple							
Singleton	8797 (98.8%)	85 (92.4%)		50 (96.2%)		35 (87.5%)	
Multiple	103 (1.2%)	7 (7.6%)	$p < 0.001^{**}$	2 (3.8%)	$p = 0.124^{**}$	5 (12.5%)	$p < 0.001^{**}$
Parity							
Primipara	4021 (45.2%)	80 (87.0%)		47 (90.4%)		33 (82.5%)	
Multipara	4875 (54.8%)	12 (13.0%)	$p < 0.001^*$	5 (9.6%)	$p < 0.001^*$	7 (17.5%)	$p < 0.001^*$
Mode of delivery							
Vaginal delivery	5180 (58.2%)	21 (22.8%)		19 (36.5%)		2 (5.0%)	
Caesarean section	3720 (41.8%)	71 (77.2%)	$p < 0.001^*$	33 (63.5%)	$p = 0.002^*$	38 (95.0%)	$p < 0.001^*$
Elective	1850 (20.8%)	42 (45.7%)	$p < 0.001^*$	17 (32.7%)	$p = 0.035^*$	25 (62.5%)	$p < 0.001^*$
Emergency	1870 (21.0%)	29 (31.5%)	$p = 0.014^*$	16 (30.8%)	$p = 0.085^*$	13 (32.5%)	$p = 0.075^*$

*p-value by χ^2 test; **p-value by Fisher's exact test**Table 6** Immediate neonatal outcome of pregnancies following assisted pregnancy methods

Outcome	Spontaneous conception (N = 8989)	Assisted pregnancy (IUI and IVF) (N = 101)		IUI pregnancy (N = 55)		IVF pregnancy (N = 46)	
	Number (%) with the feature	Number (%) with the complication	AOR, 95%CI and p-value compared to spontaneous conception*	Number (%) with the complication	AOR, 95%CI and p-value compared to spontaneous conception*	Number (%) with the complication	AOR, 95%CI and p-value compared to spontaneous conception*
Prematurity (< 37 weeks)	952 (10.6%)	34 (33.7%)	AOR: 3.04** CI: 1.90–4.88 $p < 0.001$	14 (25.5%)	AOR: 2.38** CI: 1.22–4.65 $p = 0.011$	20 (43.5%)	AOR: 4.03** CI: 2.04–7.93 $p < 0.001$
Low birth weight (< 2500 g)	1806 (20.1%)	45 (44.6%)	AOR: 1.77 CI: 1.08–2.90 $p = 0.024$	21 (38.2%)	AOR: 1.73 CI: 0.90–3.34 $p = 0.097$	24 (52.2%)	AOR: 1.83 CI: 0.86–3.86 $p = 0.114$
Small for gestational age	1793 (20.0%)	20 (19.8%)	AOR: 0.83 CI: 0.50–1.38 $p = 0.473$	13 (23.6%)	AOR: 1.14 CI: 0.60–2.14 $p = 0.688$	7 (15.2%)	AOR: 0.55 CI: 0.24–1.25 $p = 0.151$
1-minute APGAR < 8	374 (4.2%)	12 (11.9%)	AOR: 1.77 CI: 0.92–3.40 $p = 0.086$	5 (9.1%)	AOR: 1.58 CI: 0.60–4.17 $p = 0.351$	7 (15.2%)	AOR: 1.96 CI: 0.82–4.67 $p = 0.131$
5-minute APGAR < 8	113 (1.3%)	3 (3.0%)	AOR: 1.23 CI: 0.37–4.09 $p = 0.733$	1 (1.8%)	AOR: 1.10 CI: 0.12–6.81 $p = 0.927$	2 (4.3%)	AOR: 1.49 CI: 0.34–6.56 $p = 0.596$
Resuscitated at birth	552 (6.1%)	16 (15.8%)	AOR: 1.68 CI: 0.94–3.01 $p = 0.082$	7 (12.7)	AOR: 1.56 CI: 0.67–3.63 $p = 0.307$	9 (19.6%)	AOR: 1.81 CI: 0.82–4.00 $p = 0.145$
Admitted to Neonatal Intensive Care Unit	522 (5.8%)	26 (25.7%)	AOR: 2.88 CI: 1.62–5.14 $p < 0.001$	10 (18.2)	AOR: 2.26 CI: 0.97–5.25 $p = 0.058$	16 (34.8)	AOR: 3.68 CI: 1.66–8.14 $p = 0.001$
Died within the first day of life	15 (0.2%)	2 (2.0%)	AOR: 5.43 CI: 1.13–26.1 $p = 0.035$	1 (1.8%)	AOR: 5.99 CI: 0.74–48.8 $p = 0.095$	1 (2.2%)	AOR: 4.31 CI: 0.50–37.3 $p = 0.185$

* AOR- Odds ratios adjusted for prematurity and multiple births in logistic regression; ** Odds ratios adjusted for multiple births only; CI- 95% Confidence interval.

therefore, the study could not compare the stillbirth rates among assisted and spontaneous conceptions. Nonetheless, we believe the current study, conducted island-wide with a large sample size, provides valuable data on the obstetric and early neonatal complications of assisted pregnancies.

Another limitation of our study was comparing a small number of assisted pregnancies with a large number of spontaneous conceptions, which could affect the statistical analysis. Also, not having the information on the source of gametes for ART was another limitation. Considering the standard practice in the country, we assumed that all IUI are own gametes. However, a majority (75%) of IVFs were in women over 35 years old; therefore, a large proportion could be donor gamete IVF.

The findings of this study have substantial implications for antenatal and perinatal care in Sri Lanka and other low and middle-income countries. Currently, assisted pregnancies are not considered a high-risk group and are provided routine care during antenatal follow-up and delivery. Considering the high maternal and neonatal risks reported in association with assisted pregnancies in the current study, we recommend intense antenatal follow-up of assisted pregnancies with the supervision of obstetric specialists and planning of delivery at specialised centres with adequate neonatal facilities.

Conclusion

In conclusion, we found that the assisted pregnancy rate in Sri Lanka is 1%. Assisted pregnancies were significantly common among women with pregestational diabetes and hypothyroidism. Assisted pregnancies were associated with adverse obstetric complications; specifically, gestational diabetes was more prevalent among IVF pregnancies, and UTIs were more frequent in IUI pregnancies. Neonates born following assisted pregnancies were significantly more likely to be premature, low birth weight, admitted to neonatal intensive care units and die within the first day of life. Therefore, we recommend identifying assisted pregnancies as a risk group to provide more intense antenatal follow-up and arrange delivery at specialised centres with adequate neonatal facilities.

Abbreviations

ART	Assisted Reproductive Technologies
IVF	In Vitro Fertilization
IUI	Intra Uterine Insemination
UTI	Urinary Tract Infections

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12884-025-07631-y>.

Supplementary Material 1

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Author contributions

SM, HH, TD and RH conceptualised the study. SM, RM, TD, and RH performed the literature review. SM, HH and SP wrote the proposal and obtained ethical approval. SM, HH, SG, DR, AED and SP were involved in data collection. SM, RM, TD, and RH analysed data. SM, RM, TD and RH wrote the manuscript. All authors read and approved the final manuscript.

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Data availability

The dataset supporting the conclusions of this article is included within the article and its additional files.

Declarations

Ethical approval and consent to participate

All procedures performed in this study were in compliance with the Helsinki Declaration. Ethical clearance was obtained from the Ethics Review Committee of the Sri Lanka College of Paediatricians (Ref. SLCPC/ERC/2023/09). Informed consent was obtained from all study participants before recruitment. Administrative approval was obtained from the Director General of Health Services and directors of participating hospitals.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Author details

¹Department of Paediatrics, Faculty of Medicine, University of Kelaniya, Thalagolla Road, Ragama 11010, Sri Lanka

²Colombo North Teaching Hospital, Ragama, Sri Lanka

³Perinatal Society of Sri Lanka, Colombo, Sri Lanka

⁴Family Health Bureau, Colombo, Sri Lanka

⁵Department of Obstetrics and Gynaecology, University of Kelaniya, Kelaniya, Sri Lanka

⁶Department of Community Medicine, Faculty of Medical Sciences, University of Sri Jayewardenepura, Nugegoda, Sri Lanka

⁷UNICEF Sri Lanka, Colombo, Sri Lanka

⁸Ministry of Health, Colombo, Sri Lanka

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PROTOCOL

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Influence of religion and spirituality on head and neck cancer patients and their caregivers: a protocol for a scoping review

Maheeka Seneviwickrama^{1,2}, Ruwan Jayasinghe³, Kehinde Kazeem Kanmodi^{4,5,6,7*}, Simon N. Rogers⁸, Su Keill⁹, Sakuntha Ratnapreya¹⁰, Sriyani Ranasinghe², Sashini Shehana Denagamage¹ and Irosha Perera¹¹

Abstract

Introduction Head and neck cancers (HNC) are devastating, thus imposing a negative impact on the appearance of an individual as well as vital activities such as eating, swallowing, speaking, and breathing. Therefore, HNC patients undergo distress, while their caregivers become overburdened. Religion and spirituality can be helpful for patients and their caregivers from diverse cultural backgrounds to cope with cancer. Though well established in palliative care, religion and spirituality are rarely incorporated into usual early oncological care. Despite the availability of heterogeneous literature examining the influence of religion and spirituality on cancer patients, there is notably limited research on this topic across the HNC trajectory. Therefore, this scoping review attempts to answer “What is the influence of religion or spirituality on HNC patients and their caregivers in different contexts?” and will map the evidence on the influence of religion and spirituality on HNC patients and their caregivers in different contexts including geographical areas, cultures, health care systems, and different study settings.

Methods This scoping review was formulated using the guidelines of Joanna Briggs Institute (JBI) manual for evidence synthesis: scoping reviews and will be reported confirming to the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR checklist). A comprehensive search strategy will include Embase, CINAHL, Scopus, and APA PsycINFO. The OPENGREU.EU and Google Scholar will be used as gray literature sources complimented by manual searches. Our eligibility criteria follow the population, concept, and context (PCC) framework. Patients aged ≥ 18 years diagnosed with HNC and their informal, nonpaid caregivers aged > 18 years will be included. The data will be extracted using piloted data extraction form on sociodemographic, disease-related, and treatment-related factors and outcomes, and the data will be analyzed through descriptive statistics and thematic analysis. The results will be narratively synthesized.

Conclusions/discussion This review will aim to explore existing literature and summarize the findings of studies that examine the influence of religion and spirituality among HNC patients and their caregivers and vice versa over a range of physical, psychological, and social outcomes including quality of life. We also aim to identify existing research gaps. The findings of this review would generate evidence to better inform health care providers in countries and cultures in the management of patients diagnosed with HNC in usual oncological care with due consideration to caregivers.

*Correspondence:

Kehinde Kazeem Kanmodi
kanmodikehinde@yahoo.com

Full list of author information is available at the end of the article



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Keywords Head and neck cancers, Caregivers of HNC patients, Religion, Religiosity, Spirituality, Spiritual well-being

Introduction

Head and neck cancers (HNC) denotes a global public health challenge, ranking as the seventh most common cancer worldwide accounting for over 660,000 new cases and 325,000 fatalities annually [1]. Increasing incidence of HNC is attributed to rising prevalence of human papillomavirus infection and the consumption of smoked and smokeless tobacco, alcohol, and areca nut [2]. These cancers contribute to psychological distress and impaired quality of life as they involve organ systems fundamental to appearance and vital functions of daily living such as eating, swallowing, speaking, breathing, and appearance [3, 4]. Therefore, in addition to disfigurement and disruption of daily activities, the diagnosis, treatment, and sequelae of HNC are sources of distress, stigma, and anxieties [3–5]. Therefore, the sociability of not only HNC patients but also their caregivers as well could get affected [6–8]. Improvements in treatment modalities and outcomes have resulted in increasing survivorship of HNC patients, and this has created unique physical, functional, and psychosocial needs for HNC survivors when compared to survivors of other cancers [9–11]. The physical and functional needs of HNC patients include pain management, ensuring nutrition due to dysphagia, wound care, oral care, speech, and communication, while psychosocial needs comprise management of psychological distress, fear of recurrence, uncertainties, information needs, addressing body image and self-esteem concerns, emotional support, and empowerment [9–11]. Thus, the tasks of caregiving in these patients can be challenging and demanding for the caregivers, adding to a high caregiver burden. The influence of HNC are not limited to the victim alone, but its influence can affect the lives of caregivers' physically, psychosocially, and financially [10–13]. Caregivers face a range of challenges throughout the caregiving journey, which typically evolves through several phases. Initially, they may struggle with adapting to the role, feeling overwhelmed by the sudden responsibilities. As caregiving progresses, emotional and physical burdens arise, such as managing stress, coping with the patient's deteriorating health, and balancing personal life. In the later stages, caregivers may experience fatigue, financial strain, and feelings of isolation while also grappling with anticipatory grief and the emotional toll of end-of-life care. Each phase brings unique stressors, highlighting the need for targeted support systems [14]. Therefore, studies have highlighted the critical need for HNC-specific supportive care interventions for survivors as well as their caregivers [15–17].

Religion and spiritual beliefs can be very important to patients and their caregivers, regardless of their cultural backgrounds, religious traditions, and faiths [18]. Religion denotes a multidimensional, composite social construct that embraces a set of spiritual beliefs and practices manifesting at an individual level but also encompasses the institutional level through congregations which share specific beliefs, value systems, traditions, and sociocultural contexts [18]. Spiritual care is well established in the palliative care of late/advanced stage cancer patients; however, it is rarely incorporated into usual oncological care at the time of diagnosis and treatment stages with curative intent [19–22]. Adherence to structured religious rites, beliefs, and practices within a particular faith tradition can be referred to as religiosity. It frequently entails taking part in group worship and abiding by moral standards or established principles [23, 24]. Spirituality is a more expansive idea that centers on individual feelings of connection, meaning, and purpose that may or may not be connected to formal religion. Spirituality, which reflects individual views and ideals outside of official religious systems, frequently places an emphasis on personal investigation of the transcendent or sacred [23, 24]. In reality, defining both religion/religiosity and spirituality and pointing out differences between them deemed notoriously difficult [25]. Spirituality is closely connected to religion but collusively not being contained with it. Moreover, religion is liable to criticism for its archaic teachings that are patriarchal and dogmatic; imposing rules from above; being hierarchical; placing its authority in priests, bishops, and clergy; and being generally institutional, making it narrow, rigid, prescriptive, and less attractive. Separating the sacred from the profane deemed another limitation of religion, thus fostering dichotomous agenda of polarity. On the contrary, spirituality is praised for seeking the unity of the sacred, human, and the nature which largely embraces the politics, the environment, and sociocultural milieu, thus incorporating a holistic agenda.

There is voluminous research on the influence of religion and spirituality (R/S) in cancer patients, cancer care, and cancer service utilization [23–32], consequent to surge of interest in the sociocultural contributors of health and disease combined with the awareness on the importance of R/S to patients [33]. Thus, a large volume of heterogeneous literature examining the relationship between R/S and patient-reported outcomes measures (PROM) emerged in cancer research. Three meta-analyses were conducted to identify the associations between

R/S and PROM pertaining to physical, mental, and social domains [19, 27, 28, 33]. Those meta-analyses further explored and compared the strength of associations of those outcomes with dimensions of R/S broadly categorized as “cognitive,” “affective,” “behavioral,” and “other.” The cognitive dimension comprised specific R/S beliefs and perceptions, beliefs of fatalism, spiritual growth, causal attributions, attitudes of *God is responsible for one's health*, a perceived importance of spirituality, images of God, etc. The behavioral dimension consists of religious practices, private/public, meditation, mindfulness, and prayers, while affective dimension encompasses spiritual wellbeing, spiritual distress, spiritual coping, and spiritual uncertainties. R/S attributes that could not be categorized into other three categories were included as “other” which mostly comprised composite indicators of R/S [19, 27, 28, 33]. Despite the need for further research, the results generated from 1341 effects drawn from 44,000 cancer patients confirmed R/S was significantly but modestly associated with physical, mental, and social health outcomes of cancer patients. However, some dimensions of R/S were linked with more favorable outcomes while others with poorer outcomes [33]. For example, affective dimension demonstrated the largest effect size among all R/S dimensions but still modest with all health domains. In contrast, behavior dimension showed a small association only with social health domain but not with any other PROM domains [33]. Hence, the association between R/S and outcomes of cancer patients becomes complex and variable with many unresolved issues.

However, more favorable outcomes are reported by recent work on R/S and health outcomes of cancer patients across cancer trajectory. Thus, a recent systematic review on prostate cancer and spirituality revealed a remarkably positive relationship spanning to multiple positive outcomes such as reduced stress and uncertainty, less regret in the choice of treatment, functional and psychosocial well-being, empowerment of active patient participation in the treatment, and general coping with the disease [34]. Supporting this notion, a recent empirical study was conducted among a group of thyroid cancer patients found over 90% of patients perceiving that religion was crucial in their lives, with a need for praying/meditation. The patients also believed that religion offered a strong support in coping with the condition [35]. In addition, the participants in the study were interested in recovering their inner spiritual health and to strengthen the relationship with their families [35]. Therefore, cancer patients may perceive a need for spiritual health to enhance their coping skills with family support. Other studies have also explored the influence of religiosity and spirituality on caregivers of patients with

advanced cancers [35, 36]. However, clear understanding is still lacking on how patients seek to have religion and spirituality integrated into their patient-centered cancer experiences; this is confounded by marked variation in methodological approaches to studying those complex constructs [33, 37, 38].

Pertinently, there is limited research on this topic across the HNC trajectory. The limited evidence suggested positive outcomes such as better quality of life, post-traumatic growth, and less psychological distress among head and neck cancer associated with religion, religiosity, and spirituality [39–44]. However, a recent qualitative exploration assessed how certain religious beliefs, spiritual practices, and fatalism may act as barriers for timely diagnosis of oral cancers [45]. Our preliminary literature search using PubMed and Cochrane databases did not yield any scoping review, systematic review, or even a narrative review on influence of R/S on HNC cancer trajectory. Against this backdrop, it is not clear how R/S influence HNC patients and their carers across the HNC trajectory given the complexities and reciprocity involved. Hence, it is timely to assess the size and scope of the available literature, thus mapping key concepts, types of evidence, and gaps in research in this regard, through a scoping review [46]. The findings of this scoping review would generate evidence to better inform clinicians in countries and cultures in the management of patients diagnosed with HNC in routine clinical care with consideration to caregivers.

The primary aim of this paper is to document the protocol of a proposed scoping review which seeks to identify the dimensions in R/S used in HNC research and map the influence of R/S on HNC patients and their caregivers and the research gaps existing in this domain.

Methods

Title and protocol registration

The title and protocol of this proposed scoping review have been registered in the Open Science Framework registry (<https://doi.org/https://doi.org/10.17605/OSF.IO/6F4EU>).

Methodological framework

This scoping review protocol was developed based on the Joanna Briggs Institute (JBI) manual for evidence synthesis [47], which provides comprehensive guidance for developing scoping reviews, and it was underpinned by Arksey and O'Malley's [48] methodological framework for conducting a scoping review. Additionally, the guidelines of the Preferred Reporting Items for Systematic reviews and Meta-Analyses-Protocol (PRISMA-P) checklist were used for the reportage of this protocol [49].

Stage 1: Identifying the review question

The primary research question for the proposed review is “What is the influence of religion or spirituality on HNC patients and their caregivers in different contexts?” Further, the primary research question was further divided into these specific sub-questions, based on the specific objectives of the proposed review:

1. What are the dimensions of religion and spirituality used in HNC research?
2. What is the influence of religion or spirituality on HNC patients and their caregivers on a range of physical, psychological, and social health outcomes including quality of life, health-seeking behaviors, treatment outcomes, treatment compliance, and survival?
3. What is the influence of cancer diagnosis and cancer trajectory experiences on religion and spirituality of HNC patients and their caregivers?
4. What are the existing research gaps in the area of HNC and religion or spirituality?

Stage 2: Identifying the relevant studies (search strategy)

A comprehensive search will be conducted without a time restriction to identify relevant literature in the following electronic research databases: Embase, MEDLINE, CINAHL, and APA PsycINFO. Reference lists of included articles will also be examined to identify any additional literature. Google Scholar (databases of gray literature) will be manually searched to complement the search strategy. Corresponding authors of the selected literature will be contacted if further information is required. The search strategy will be rerun 4 weeks prior to submission of the manuscript for publication to capture the latest literature.

The literature search strategy will be developed through an iterative process by a multidisciplinary team including a librarian and health knowledge services expert, a consultant oral and maxillofacial surgeon, an academic in pediatric dentistry, a consultant in community dentistry, and two public health specialists with experience in conducting systematic reviews. The review questions will be disaggregated into key concepts to facilitate comprehensive and robust search strategies. In addition to Medical Subject Headings (MeSH) terms, appropriate keywords will be identified through commonly used phrases stated in related literature to capture constructs of religion, religiosity, and spirituality among HNC patients. First, the search strategy will be developed for PubMed search, and then the same strategy will be applied with relevant modifications to the other databases. Our initial search strategy is as follows:

Head OR Neck OR “Nasal Cavity” OR “Paranasal Sinus*” OR “Skull Base” OR Nasopharynx* OR Salivary OR Craniopharynx* OR Neuroendocrine OR Hypopharynx* OR Larynx* OR Trachea* OR Parapharynx* OR Oral OR Tongue OR Oropharynx* OR Odontogenic OR Extramedullary.

AND

Cancer* OR Malignant* OR Tumour OR Tumor OR Lesion OR Neoplas* OR Neuroblastoma OR Meningioma OR Chondrosarcoma.

AND

Religio* OR Spirit* OR Faith OR Multifaith OR “Mind–body” OR Meditation OR Mindfulness OR “Spiritual coping” OR “Religious coping” OR Pray OR Pastor* OR Belief OR Believe* OR Heal* OR yoga OR meditat*

Search strategy used for each database with the results will be presented as a supplemental material.

Stage 3: Study selection**Eligibility criteria**

This proposed scoping review will follow the population, concept, and context (PCC) framework to define eligibility criteria, as recommended by the Joanna Briggs Institute (JBI), to facilitate a more focused literature search [47].

The population will include adults 18 years or older with a histologically confirmed diagnosis of HNC which could be primary, recurrent, or metastatic deriving from paranasal air sinuses, nasal cavity, oral cavity, salivary glands, pharynx, or larynx. Patients with brain, esophageal, thyroid, and parathyroid cancers will be excluded as they are not considered to be typical HNC cancers [50]. Furthermore, formal and informal adult caregivers (18 years or older) of HNC patients will be included. The core concept refers to the influence of religion and spirituality on HNC patients and their caregivers. The subconcepts will include the relationships of cognitive, affective, behavioral, and other dimensions of religion and spirituality (as described in the introduction section of this paper) on self-reported and objectively assessed physical, mental, and social health outcomes and related constructs including quality of life. The context for this proposed review will include all countries and study settings such as primary care, secondary care, tertiary care, hospices, home-based care, and community settings (Table 1).

In addition to the use of the PCC framework, study design, language of publication, and publication type will also inform the review’s eligibility criteria. Only those qualitative studies (ethnographic studies, phenomenological

Table 1 PCC framework for developing the review’s eligibility criteria

Criteria	Characteristics
Population (P)	Adults with a histologically confirmed diagnosis of HNC which could be primary, recurrent, or metastatic deriving from paranasal air sinuses, nasal cavity, oral cavity, salivary glands, pharynx, or larynx
Concept (C)	The influence of religion and spirituality on HNC patients and their caregivers
Context (C)	Context of care including all countries and study settings such as primary care, secondary care, tertiary care, hospices, home-based care, community settings

studies, etc.), quantitative studies (clinical trials (randomized and non-randomized), cross-sectional studies, case-control studies, and cohort/longitudinal studies), mixed-methods studies published in English and as a peer-reviewed journal article or thesis or book chapter or full-length conference paper will be included in the proposed review.

Defining religion, religiosity, and spirituality

Below are the definitions of religion, religiosity, and spirituality in this proposed scoping review.

Religion is a multidimensional construct that includes beliefs, behaviors, rituals, and ceremonies that may be held or practiced in private or public settings but are in some way derived from established traditions that developed over time within a community. Religion is also an organized system of beliefs, practices, and symbols designed to facilitate closeness to the transcendent and to foster an understanding of one’s relationship and responsibility in coexisting with others [23, 24].

Spirituality is defined as set of all emotions and convictions of a nonmaterial nature with the assumption that there is more to living than can be perceived or fully understood, referring to questions such as the meaning of life, not limited to any type-specific religious belief or practice. Spirituality includes both a search for the transcendent and the discovery of the transcendent and so involves traveling along the path that leads from non-consideration to questioning to either staunch nonbelief or belief, and if belief, then ultimately to devotion, and, finally, surrender. Thus, our definition of spirituality is very similar to religion, and there is clear overlap [23, 24].

Literature selection process

Identified records will be uploaded into the Rayyan web tool for record management [51], and the duplicates will be removed. Titles and abstracts will be screened based on the inclusion and exclusion criteria by two independent reviewers. Disagreements in literature selection decisions will be resolved by a third reviewer. The same procedure will be carried out with the full-text level

screening. The record review and selection process will be illustrated using a PRISMA flow diagram [49].

Critical appraisal

Included studies will be critically appraised using the Joanna Briggs Institute critical appraisal tools [52]. Two reviewers will independently undertake the appraisal and comment on each criterion. Disagreements will be resolved by discussion between reviewers, failing which by consulting a third member of the review team for arbitration. This is not to exclude studies but to provide context to the analysis. The level of credibility of the included studies will be presented in a table.

Stage 4: Charting the data

Data will be extracted and entered into a bespoke data extraction sheet developed by the review team. Data items of interest were structured based on the review’s eligibility criteria and the objectives of the study. From each selected literature, the following information will be extracted: author names, year of publication, title of literature, study location, objectives of the study, study design, study setting, study period, study population, sample size and sampling technique, data collection method including measurement of religion/religiosity or spirituality, reported influence of religion/religiosity or spirituality on construct being measured, and limitations. To ensure quality of the data extraction process, data from the first five documents will be extracted as a training stage by all reviewers independently, and the results will be compared. The data of the remaining selected literature will be extracted by two independent reviewers. These two sheets will be compared, and any inconsistencies will be discussed and adjudicated by a third reviewer if required. In case further information or clarification is needed concerning the extracted data, the corresponding authors will be contacted (Supplementary files 1 & 2).

Stage 5: Collating, summarizing, and reporting of results

The data charted in this scoping review will be collated and summarized in themes and presented as texts, charts, and tables, using a narrative synthesis approach.

Findings of each included study will be presented with key characteristics such as first author, year of publication, geographical location, study design, sample size, and sampling method (Table 2). Results will be reported according to the review questions. To answer the first question (What are the dimensions of religion and spirituality used in HNC research?), results will be presented as a narrative review with regard to affective, behavioral, cognitive, and other such as multidimensional psychometric scales. Further details will be provided under “Measurements” of Table 3.

Answers to the second (What is the influence of religion or spirituality on HNC patients and their caregivers on a range of physical, psychological, and social health outcomes including quality of life, health-seeking behaviors, treatment outcomes, treatment compliance, and survival?) and the third (What is the influence of cancer diagnosis and cancer trajectory experiences on religion and spirituality of HNC patients and their caregivers?) questions will be described as a narration. Additionally, this information will be presented in Table 3 under “Findings.”

Identification of the existing research gaps and limitations in the relationship between religion/spirituality (R/S) and HNC is essential to address the fourth sub-question of this review: What are the existing research gaps in the area of HNC and religion or spirituality? Given the limited yet evolving research arena on the influence of R/S on HNC trajectory, it is important to make a note of existing limitations and research gaps to influence future research work with better translational value. This will encompass mining into study designs, the

complex reciprocal relationship between R/S and HNC trajectory, the internal and external validity of study findings, and controlling for confounding factors such as socioeconomic status, disease-related factors, and treatment-related factors. For example, cross-sectional study designs reflect a snapshot of a single time point instead of a sequence of events (whether R/S variables or changes in R/S variables predict health outcomes across the cancer trajectory), thus necessitating longitudinal follow-up studies for more conclusive evidence. By taking stock of existing research, gaps in the perceived influence of patients and caregivers on integrating R/S into usual HNC care will be identified.

The potential limitations of evidence synthesis method of this scoping review will also be discussed.

Expected outcomes

The influence of religion, religiosity, or spirituality on the following domains of the patients diagnosed with HNC and their caregivers will be described in the proposed scoping review:

1. Quality of life
2. Survival
3. Physical well-being
4. Psychological well-being
5. Social well-being
6. Posttraumatic growth
7. Adjustment
8. Appearance concerns
9. Cancer diagnosis
10. Fatalism
11. Treatment compliance
12. Demoralization
13. Depression
14. Anxiety
15. Suicidal ideation
16. Sleep disorders
17. Fatigue
18. Timely access of health care services
19. Any other outcome not mentioned before

Table 2 Study characteristics

Heading	Data extraction
Study details	Author, year, country
Study design	Qualitative, case study, observational, cross-sectional, case control, etc
Participant characteristics	Study population, sample size

Table 3 Measurements used, reported influence on HNC, and limitations of studies

Heading	Data extraction
Study details	Author, year, country
Measurements	Data collection method including measurement of religion/religiosity or spirituality
Findings	Reported influence of religion/religiosity or spirituality on construct being measured Reported influence of cancer diagnosis and cancer trajectory experiences on religion and spirituality
Limitations	Reported limitations in studies

Discussion

The primary research question and aim of this scoping review are to explore and expound the multifaceted influence of religion and spirituality among HNC patients and their caregivers in different contexts, across an array of outcomes ranging from quality of life to health care-seeking behavior. Further, we shall be dissecting this influence along cancer trajectory from diagnosis to palliative care with the special emphasis to usual HNC oncological care. Reciprocally, we aim to explore the influence of cancer diagnosis and cancer trajectory on religion and spirituality of HNC patients and their caregivers. We shall be attempting to identify and compare the influence of dimensions of religion and spirituality, i.e., cognitive, affective, behavioral, and other on domains of health and other outcomes in HNC trajectory. Given the aerodigestive anatomic involvement of the tumor as well as its treatment affecting the appearance and vital activities of daily living such as eating, speaking, breathing, and swallowing, inevitably, HNC patients need to cope up with the devastation, discomfort, and distress, while their carers need to grapple with challenging task of caregiving. Hence, there is an emerging need to explore the potential of religion, and religiosity and spirituality could offer to relieve the suffering of HNC patients and their overburdened caregivers. Due to the meticulously crafted eligibility criteria and the wide range of terms proposed for the search strategy, this scoping review would generate a wealth of evidence unravelling not only the complexities in conceptualizing, defining, and measuring the composite constructs of religion, religiosity, and spirituality but also their complex influence on HNC patients and their caregivers highly confounded by countries, cultures, and health care systems. We shall identify existing knowledge and research gaps and challenges in the milieu of influence of religion, religiosity, and spirituality on HNC patients and their caregivers. Our findings will shed light into better approaches in integrating religious and spiritual care to patient-centered cancer care experience of HNC patients and their caregivers.

Implications for research and practice

The findings of this review will have important implications for both research and practice. New research should focus on addressing the gaps identified in this review. Recommendations for practice changes at various levels of service delivery related to R/S domains will be provided based on key findings in the review. HNC patients and their caregivers undergo unique challenges and elevated psychosocial supportive care needs throughout cancer trajectory as the disease and its treatment

negatively impact on vital functions of the daily life of patients such as eating, swallowing, breathing, and speech. Those needs often become unmet and navigating religion and spirituality to enhance psychosocial and mental well-being of HNC patients and their caregivers and their coping strategies. Given the poor prognosis of many types of HNC and the perception of deadly nature of cancer, patients and their caregivers often experience spiritual needs upon receiving cancer diagnosis. Findings of this scoping review will provide novel insights on incorporating religion and spirituality to comprehensive cancer care for HNC patients and their caregivers by fostering supportive environments for patient-centered care across countries, cultures, and health systems.

Strengths and limitations

This is the first scoping review synthesizing evidence on the influence of religion and spirituality on HNC patients and their caregivers. Comprehensive search strategy developed through an iterative process involving experts from relevant fields will enable us to provide a broad overview of the subject.

Despite already published scientific literature on the influence of religion and spirituality on head and neck cancer patients and caregivers which are often positive, yet negative or inconclusive at times, to this date, there is no scoping review that critically synthesizes the evidence that aims to map key concepts in the complex multidimensional constructs of religion and spirituality as well as an array of outcomes that are physical, psychological/emotional, social, and perceived quality of life, the type of evidences and gaps in published research in this broad research arena with many unresolved issues. Given the unique challenges that arise in the holistic management of head and neck cancer patients compared with patients with other cancer types, attributed to the negative impact on vital functions of daily living such as eating, breathing, swallowing, and speaking as well as appearance and self-identity caused by the disease and its treatment, religion and spirituality have garnered recognition as novel approaches in managing head and neck cancer patients. Therefore, we believe that addressing this existing knowledge gap would facilitate clinicians and health care providers to incorporate religion and spirituality to the holistic management protocols of head and neck cancer patients, thus embracing innovative approaches, and to address unmet supportive care needs of caregivers of those patients across cultures, countries, and health systems.

Inclusion of literature published only in the English language will be a limitation of this review.

Abbreviations

HNC	Head and neck cancers
DSES	Daily Spiritual Experience Scale
PRISMA-ScR	Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews
PRISMA-P	Preferred Reporting Items for Systematic reviews and Meta-Analyses-Protocol
MeSH terms	Medical Subject Headings terms

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13643-025-02768-5>.

Supplementary Material 1. Influence of religion and spirituality on head and neck cancer patients and their caregivers: a protocol for a scoping review

Supplementary Material 2. Influence of religion and spirituality on head and neck cancer patients and their caregivers: a protocol for a scoping review

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Centre for Cancer Research, University of Sri Jayewardenepura, Nugegoda, Sri Lanka

Authors' contributions

Review question was identified by IP and SNR. Search strategy was drafted by IP and MS and was modified by SNR, SK, KKK, SaR, RJ, and SrR. The study was designed by MS, IP, and SSD and modified by KKK and RJ. Manuscript was drafted by SSD, MS, and IP. All authors substantially contributed to the revision of the manuscript and approved the final version.

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Data availability

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

Declarations

Ethics approval and consent to participate

This scoping review is not subjected to research ethics board approval as there will be no direct participant contact or data collection at an individual level. Dissemination of the findings will include the publication of a scoping review manuscript in an open-access journal to reduce barriers and provide ease of access to a wider stakeholder audience. Knowledge translation will further include presentations at national and international conferences with clinical audiences. Patients, caregivers, and the public were involved in the designing of this scoping review protocol as patient and caregiver experience in religion, religiosity, and spirituality in cancer trajectory is fundamental to exploring and expounding their relationships.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Author details

¹Centre for Cancer Research, University of Sri Jayewardenepura, Nugegoda, Sri Lanka. ²Department of Community Medicine, Faculty of Medical Sciences, University of Sri Jayewardenepura, Nugegoda, Sri Lanka. ³Department of Oral Medicine and Periodontology, Faculty of Dental Sciences, University of Peradeniya, Peradeniya, Sri Lanka. ⁴School of Dentistry, University of Rwanda, Kigali,

Rwanda. ⁵Faculty of Dentistry, University of Puthisastra, Phnom Penh, Cambodia. ⁶School of Health and Life Sciences, Teesside University, Middlesbrough, UK. ⁷Cephas Health Research Initiative Inc., Ibadan, Nigeria. ⁸Oral and Maxillofacial Department, Wirral University Teaching Hospital NHS Foundation Trust, Liverpool, UK. ⁹Library & Knowledge Service, Wirral University Teaching Hospital NHS Foundation Trust, Liverpool, UK. ¹⁰Division of Paedodontics, Department of Community Dental Health, Faculty of Dental Sciences, University of Peradeniya, Peradeniya, Sri Lanka. ¹¹Preventive Oral Health Unit, National Dental Hospital (Teaching) Sri Lanka, Ward Place, Colombo 7, Sri Lanka.

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