



Management of intestinal failure in middle-income countries, for children and adults

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Purpose of review

Intestinal failure is a life-threatening medical condition that remains as a rare or orphan disease in most countries. The prevalence of intestinal failure and the therapeutic options available in middle-income countries (MIC) remain unclear. We aim to provide an overview on the current differences in management of intestinal failure patients in MIC from Latin America and Asia.

Recent findings

In order to fulfil the challenge, and after facing the difficulties of going over a topic with scarce available data, from countries with an extreme variety of social and economic problems, which are closely related to the treatment of intestinal failure patients, we have used both the existing publications and personal surveys to draft this document. Our results have shown that there is still significant disparity among MIC over the last years, concepts such as the need for establishing multidisciplinary dedicated teams as well as the need to evolve first home parenteral nutrition (HPN), then rehabilitation, and finally transplantation, have become important signals of an adequate understanding of this evolving field.

Summary

The manuscript presents, for the first time, an overview of the different developments and needs to manage intestinal failure patients in MIC from Latin America and Asia. Future discussions will emerge from this manuscript, aiming to pursue the development of registries, guidelines and health policies to continue improving the long-term care of intestinal failure patients in all MIC.

Keywords

home parenteral nutrition, intestinal failure, intestinal transplantation, Latin- America, rehabilitation

INTRODUCTION

Intestinal failure is a life-threatening medical condition, which should be similar among countries worldwide, however the disparity of medical care available or access to healthcare, the different social environments, the severity of the affected bowel at presentation and the lack of registries, turn assessment into a difficult matter. Although described and recognized for many years, hard work is still required in order to agree whether intestinal failure should be included as a rare or orphan disease in most countries [1^{*,2}]. Middle-income countries (MICs) have been defined as nations with a per-capita gross income between 1036 and 12 615 US\$ (<https://www.investopedia.com>). Following this economic definition, MICs are a very diverse group by size, population and income level, ranging from small nations, such as Belize to some of the largest countries in the world, such as India or China. MIC contain five-seventh billions of the total health population (<https://www.investopedia.com>).

Accepting the challenge of writing this review, we face the difficulties of going over a topic with a scarce number of publications; therefore, we have used them as well as personal surveys in order to provide a preliminary start-up overview on the current situation and the differences in management of intestinal failure patients in MIC from Latin-América and Asia. Future discussions will emerge from this manuscript, aiming to pursue the development of registries, guidelines and health policies to continue

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KEY POINTS

- Intestinal failure remains as a rare or orphan disease for MIC in LA and Asia, with a very significant disparity among them; most lack HPN and few actively perform ITx.
- The need to establish multidisciplinary dedicated teams, and the need to evolve first HPN, then rehabilitation and finally transplantation, have become important signals of an adequate understanding of this evolving field in MIC.
- Registries need to be developed to continue understanding the different realities in order to pursue the development of registries, guidelines and health policies to improve accessibility to long-term care of intestinal failure patients in all MIC.

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MANAGEMENT OF INTESTINAL FAILURE IN LATIN AMERICA

Latin America and the Caribbean constitute two-third of the total surface of the American continent, with a total population of 650 000 000 million inhabitants, distributed among 42 countries (<http://www.prb.org>). All of them have patients diagnosed with intestinal failure, but few (two out of 42, 4.76%) are currently capable of providing sustained and complete care, ranging from home parenteral nutrition (HPN) to intestinal transplantation (ITx) (<http://felanpeweb.org>). The main causes of intestinal failure for adults in our latitudes are postsurgical complications followed by mesenteric ischemia, while in high-income countries, the main causes are Cronh's disease followed by mesenteric ischemia, and in the third place, postsurgical complications. The main causes of intestinal failure in children are intestinal atresia, gastroschisis and volvulus; necrotizing enterocolitis (NEC) is the fourth most common cause in our latitudes, while it is the first one in Europe and the US, probably as consequence of better survival in extremely premature newborns [3]. The following paragraphs will provide current data on HPN, intestinal rehabilitation and transplantation.

Home parenteral nutrition in Latin America

Although it has been established that the first and gold standard therapy for patients with intestinal failure is HPN (a therapy developed by Dudrick, Wilmore, Vans and Rose in the 60s [4]), this therapy is still not available in all Latin American countries;

therefore, many patients suffer not only from having the disease that caused the intestinal failure but also from having the impossibility of receiving the first-line therapy, thus increasing their early mortality risk. The FELANPE (Latin American Federation of Parenteral and Enteral Nutrition), the most recognized society in Latin America responsible for engaging experts on parenteral nutrition and HPN, with 17 participating Latin American countries, shows that currently only five (29.4%) have HPN (<http://felanpeweb.org>), and although there are no official data, many countries still do not have parenteral nutrition. This uncovered need has multiple causes, ranging from lack of expertise to either prescribe or produce it; to lack of the financial support required to have accesses to the different providers. On the basis of a recent personal survey performed among all physicians included in the acknowledgement and presented at the Congress of the Intestinal Rehabilitation and Transplant Association 2017 (CIRTA 2017, held in New York last June), we were able to gather the following data regarding the number of patients on HPN up to June 2017: Argentina had 281 patients including adults (186, 66.2%) and children on HPN, provided by three private companies (Fresenius-Kabi, Centro de Mezclas y Lativ) and one paediatric public hospital (Hospital de Niños Sor María Ludovica de la Plata) [3,5]; only 9.96% out of them were oncological patients; Colombia had 76 patients on parenteral nutrition (with a lack of definition regarding the exact number on HPN), solutions are prepared at public hospitals; Brazil had 53 patients (Adults and Pediatrics) on HPN; Chile reported 50 patients on HPN, most of them provided by a private company [6]; Peru has evolved over the last years achieving a total number of 14 patients on parenteral nutrition, some of them on transient HPN, while Uruguay had 12 patients provided mainly by a private company (Libra). The reduced number of patients in some Latin American countries is a consequence of their recent development (Table 1). Over the last 10 years in Latin America, there has been a favourable change in the approach to this rare disease, favouring the need of establishing multidisciplinary intestinal failure rehabilitation and transplant programmes as devoted teams [7,8]. However, only a few of them have reported the impact of lacking such programmes. As an example of the importance of reporting results, Brazil has recently published 25% 5-year survival of adult intestinal failure patients managed on HPN [7]; the awareness of the problem helped to take actions, and the Brazilian Health Ministry has agreed to provide support for developing an IF Registry, and to establish

Table 1. Summarizes the number (#) of patients on HPN, # of SR procedures and # of IT

HPN			
Country	No. of patient on HPN	No. of population	Ratio ^a
Argentina	281	41 600 000	6.75
Uruguay	12	3 300 000	3.60
Chile	50	16 900 000	2.95
Colombia	76	47 400 000	1.60
Peru	14	30 650 000	0.45
Brazil	53	202 900 000	0.25
Mexico	NA	131 400 600	–
Costa Rica	NA	4 900 000	–
Total	486	–	–
Surgical rehabilitation (SR)			
Country	No. of SR procedures AGIRS/STEP	No. of population	Ratio ^b
Argentina	134/45 (179)	41 600 000	4.30
Uruguay	6/2 (8)	3 300 000	2.40
Peru	46/0 (46)	30 650 000	1.50
Chile	11/5 (16)	16 900 000	0.95
Colombia	36/1 (37)	47 400 000	0.80
Brazil	94/10 (104)	202 900 000	0.50
Mexico	NA	131 400 600	–
Costa Rica	NA	4 900 000	–
Total	390	–	–
Intestinal transplant (ITx)			
Country	No. of IT	No. of population	Ratio ^c
Argentina	56	41 600 000	1.35
Colombia	38	47 400 000	0.80
Costa Rica	1	4 900 000	0.20
Chile	2	16 900 000	0.10
Brazil	13	202 900 000	0.05
Mexico	2	131 400 600	0.01
Peru	0	30 650 000	–
Uruguay	0	3 300 000	–
total	112	–	–

^aNo. of patients on HPN per million habitants up to June of 2017.

^bNo. of SR procedures did per million habitants up to June of 2017.

^cNo. of ITx did per million habitants up to June of 2017.

intestinal failure programmes; up today, they have provided financial support for two programmes, one for adults in Sao Paolo, and one for children in Porto Allegre. In Uruguay, there is work in progress to establish intestinal failure programmes in two public institutions. In Colombia, a recent report from a single paediatric centre in Medellin shows that in 2005, a multidisciplinary team was established for children, and although they have achieved 69.7% on intestinal rehabilitation, and they have ITx programmes, they still need to evolve HPN [9]. Argentina has proved to be the most evolved country, covering the full variety of treatment options for patients with intestinal failure.

A progressive evolution over the last 30 years was necessary, starting by establishing paediatric and adult HPN programmes, but working simultaneously on different tools (that could serve as examples for other countries in our region) in order to sustain the care achieved and to improve quality in other areas to be able to reach complete therapeutic options for intestinal failure patients. Healthcare professional can be part of the local association called AANEP (Argentinean Association for Enteral and Parenteral Nutrition; <http://www.aanep.org.ar>), which has developed national guidelines for managing patients on parenteral nutrition and HPN (Ministry of Health, Resolution Number 1548/

2007); there is also a law for visceral disability that provides health coverage for all treatment strategies for patients with chronic intestinal failure, from HPN to ITx.

Medical rehabilitation in Latin America

Intestinal rehabilitation should be considered as the main goal to restore enteral autonomy in MIC. It will assure recovery of quality of life, discontinuing HPN and avoiding the need for long-term use of immunosuppressive drugs [10,11].

In most Latin American countries, medical rehabilitation starts after surgical rehabilitation. The importance of team approach to rare diseases must be highlighted. The goal of the joint effort is to recognize the new postsurgical anatomo-physiology, in order to optimize and maximize digestion and absorption, combining multiple complementary nutritional and pharmacological strategies such as antisecretory, antimotility drugs and antibiotics, among others [12]. Although medical rehabilitation seems to be offered in most of Latin American countries, there is lack of data to assess how many of these patients with a particular anatomy are able to reach intestinal sufficiency and are capable of being off HPN. In Chile, the team of the Catholic University Hospital IF, Rehabilitation and Transplant programme reported their experience from 2009 to 2015, with 14 patients with short bowel syndrome (SBS) who benefited from medical and surgical rehabilitation, achieving intestinal autonomy in 13 of them [13].

An initial report from our centre, including 250 adult patients with intestinal failure, showed that 74.1% of them with intestinal remnant more than 50 cm after autologous gastrointestinal tract reconstructive surgery (AGIRS) were able to achieve intestinal autonomy within 5 years after the procedure. No patients with intestinal length less than 50 cm lacking ileo-cecal valve were able to be off HPN, with combined surgical and medical therapy until 2014 [14]; the possibility to start treating these patients with enterohormones such as glucagon-like peptides (GLPs) 1 and 2 opens a new alternative. Teduglutide, a GLP-2 analogue, has provided the chance of offering rehabilitations to patients with intestinal failure type III, to further change the outcomes [15]. Although the drug in Latin America is still not commercially available, we have requested to be used it as compassionate use. From January 2015 to June 2017, we have had six adult patients receiving GLP-2 analogue; five of them are currently off HPN with treatment span ranging from 5 to 54 weeks. This new therapeutic possibility has increased the chances to achieve freedom from HPN in our cohort, improving not only long-term

survival and reducing HPN-related complications, but also more importantly, improving quality of life by offering freedom [16].

Surgical rehabilitation in Latin America

Surgical management in order to establish intestinal sufficiency in children and adult patients has evolved over the last 10 years in Latin America [7–9,13]. On the basis of our survey, approximately 390 procedures have been performed in dedicated intestinal failure programmes (Table 1). Similar procedures have been done by paediatric and general surgeons in other institutions that are not part of the numbers collected by us; future surveys are being developed, aiming to obtain the complete cohort of patients receiving lengthening procedures. From our survey, we were able to learn that the use of serial transverse enteroplasty (STEP) appears as the dominant procedure performed in children, while the AGIRS has become the preferred procedure performed in the adult population. Five centres in Brazil have performed 104 procedures up to May 2017, including 94 AGIRS and 10 STEPS; in Colombia, 37 patients have undergone rehabilitation surgery, 36 AGIRS and one STEP in two centres. In Chile, 16 procedures have been reported, 11 AGIRS and five STEPS among five centres, while in Uruguay over the last 3 years, eight procedures were performed in six centres, including six STEP and two AGIRS. In Peru, from 2011 to 2017, a total of 110 patients with intestinal failure were centralized in two centres, one for adults and one for children; 46 out of them have received rehabilitation surgery, all of them AGIRS. In Argentina, two centres are able to provide the whole care from HPN to Transplantation, and up to May 2017, 179 rehabilitation surgeries have been performed by them, including 36 STEPS, nine re-STEPS and 134 AGIRS. A recent study from the Italian Hospital on children shows that 27 out of 39 patients received surgery, 12 STEPS and 17 AGIRS; 18 patients out of the total have achieved intestinal sufficiency [17]. In our centre, a follow-up study of our initial series of 71 adult patients with intestinal failure receiving AGIRS shows that 47 patients (66.2%) were able to achieve intestinal autonomy within 2 years after the procedure, and 76% at 5 years; the possibility of adding GLP-2 therapy, since 2015, has increased the chances of achieving freedom from HPN up to 83%, for the same cohort, as it was mentioned in medical rehabilitation [18].

Intestinal transplantation in Latin America

Brazil has been the pioneer country for ITx, starting in 1968 [12], 1 year after Richard Lillihei's first case in Minnesota [19]. In 1998, the first ITx was

performed in Argentina, in 1999 in Mexico, in 2002 in Colombia and in 2004 in Chile. In 2011, the first living donor intestinal transplant was performed in Mexico [20]. The common factor among these pioneer efforts was to offer ITx as an alternative to HPN in intestinal failure patients. Most of them were performed by surgeons lacking multidisciplinary programmes to support and manage intestinal failure patients. In 2006, Colombia and Argentina established intestinal failure rehabilitation and ITx programmes, being able to increase and sustain the number as well as the variety of procedures performed, from isolated ITx to combined liver intestinal transplant, multivisceral (MTV) and modified multivisceral (mMTV) in adults and children. Up to May 2017, a total of 112 ITx were done in Latin America, 89 isolated, five combined, 14 MTV and three mMTV (Table 1). Currently, well established programmes are able to obtain long-term survivals comparable to the ones reported by the international intestinal registry and by programmes from high-income countries. Indications for Itx have moved from offering transplant as an alternative to HPN to follow the international accepted indications. A recent manuscript published by a public paediatric institution that was not able to offer bowel-lengthening procedures (STEP) or transplantation in Argentina, before 2006, published their 30-year experience, proving the benefit of having access to both therapies in a select group of children ($N=155$), with neonatal short gut syndrome, being able to obtain a mortality reduction overtime from 31% (1985–1994) to 13.8% (2005–2014), with a current patient survival of 90 and 81% at 1 and 5 years, respectively [3]. After 2009, other countries such as Chile, Peru and Brazil have started to follow the same pattern [7–9,13]. Following the initial statements in the current manuscript, healthcare realities are very different among Latin American countries, but it is necessary to understand that when an intestinal failure patient is diagnosed, the first treatment to be offered is HPN, while the last one should be ITx. Physicians as well as medical societies and governments should work together in order to establish the need to assure HPN in every country in Latin America. They should continue training physicians and surgeons to be able to provide medical and surgical intestinal rehabilitation, and finally to establish cooperation among countries in order to have a limited number of centres available only in the most technically developed countries of Latin American MIC. This decision will help to sustain volume and to improve results at high-quality ITx programs.

MANAGEMENT OF INTESTINAL FAILURE IN ASIA

Asia constitutes 8.70% of the total land surface of the Earth, with a total of 44.6 million km² and a population of 4 478 315 000 million inhabitants, distributed in 48 countries, 41 Asian countries and seven Euro-Asian countries (<http://poblacion.population.city/world/as>).

Home parenteral nutrition in Asia

HPN seems to have low applicability in Asian countries. The most common indication for parenteral nutrition in adults is SBS secondary to mesenteric ischemia, postsurgical complications, followed by cancer. Paediatric causes are similar to those of other regions worldwide. Like in Latin America, inflammatory bowel diseases are less common compared with US and Europe [21]. In spite of some publications, it is very difficult to find reports and registries covering the existence or the development of HPN in Asian countries. The Parenteral and Enteral Nutrition Society of Asia (PENSA), created in 1995 by a group of physicians from Japan, China, Indonesia, Malaysia, Philippines, Pakistan and Thailand, provides continuous medical education, and has set a forum to address and exchange experiences in nutritional support; however, it lacks data reports (<http://www.pensa-online.org>). In most Asian MIC, HPN is prepared by national hospitals; for example, in Taiwan, in 1989, the Nutritional Support Service (NSS) was created for adults and children, in order to provide services in most hospitals under the supervision of the Taiwan Society of Parenteral and Enteral Nutrition (TSPEN); TSPEN is supported by the Bureau of National Health Insurance. They report that from 1989 to 2011, 64 patients with intestinal failure were evaluated and started on HPN [22–24]. In 2006, a survey was conducted by the Japan Society for Home Therapy Research and it was sent to hospitals providing HPN, 66 respondents from 345 institutions stated that more than 50% of the staff involved had more than 10 years of experience, 14 institutions reported to have more than 50 patients on HPN, and 80% of the respondents had oncological patients as the main indication; 50% of them were prepared in house, and 12% were prepared by home care service providers. The manuscript also reports that lipid emulsions are not adequately used in Japan, with 28% of the respondents using them only when patients are hospitalized [25]. Wu *et al.* [26] reported for the first time prevalence and complications in adult patients with SBS receiving HPN in China, 47 patients received HPN over a 2-year period, experiencing a low rate of catheter-related sepsis (0.31 ± 0.05 per catheter/

year) but a high incidence (53.2%) associated liver/biliary disease. During CIRTA 2017, Dr Lee M, in a personal presentation reported that in Asia, there are eight HPN-dedicated centres in China, six in India, more than five in Japan, five in Korea and 19 in Taiwan. In some centres, ITx has been offered as an alternative to HPN, as it was mentioned in the Latin American session.

Medical and surgical rehabilitation in Asia

To the best of our knowledge, there is a lack of data published regarding the existence or development of medical or surgical rehabilitation programmes in Asia.

Shiraz Medical Center in Iran has recently established an Intestinal Failure, Rehabilitation and Transplant programme aiming to provide state of the art care for intestinal failure patients, performing over the last 4 months 5 AGIRS in adult patients (unpublished data).

Intestinal transplantation in Asia

Intestinal transplant activity started in Asia in 1996, in Japan, with a living donor, while the first cadaveric donor intestinal transplant was performed in 2001. Since then, ITx has evolved in Korea (four centres), China (eight centres), Taiwan (one centre), India (two centres), Iran (one centre) and Turkey (one centre). The last report from Asia presented at CIRTA 2017 showed that 162 ITx had been done in Asia (Table 2); 72% were isolated ITx and 14.2% followed by MVT. Out of the total number of cases, 18 LRD ITx were done, seven in China, seven in Japan and four in South Korea. The same report mentions the use of donors after cardiac death for ITx in China ($N=30$); long-term results are not mentioned.

The overall 1 and 5-year patient's survival ranges between 50–88 and 42–70%, respectively, and 1 and 5-year graft survival ranges between 50–81 and 42–60%, respectively. There are no available survival data from China.

CONCLUSION

Although there is an evolution in the development of intestinal failure treatment in MIC countries in Latin America and Asia, this issue remains as an unresolved health problem. Physicians still need to be educated on the concept that parenteral nutrition and HPN are the first line of treatment to be evolved, followed by medical and surgical rehabilitation and, finally, ITx. Intestinal failure patients are complex and very demanding, and they require long admissions as well

Table 2. Total of intestinal transplants per country

Country	ITx	No. of population	Ratio ^a
Taiwan	21	23 600 000	0.90
Iran	43	81 600 000	0.50
Korea	22	50 900 000	0.45
Japan	27	125 250 000	0.20
China	47	1 390 900 000	0.03
India	2	1 350 500 000	0.001
Total	162	–	–

IT, intestinal transplant.

^aNo. of IT performed per million habitants up to June of 2017.

as frequent readmissions. Therefore, the existence of a multidisciplinary team is the key to succeed, and the inclusion of a social worker and a psychologist as part of the multidisciplinary team must be considered in order to help patients to have accesses to the necessary financial support, and to assure compliance with follow-up and treatment. Regional strategies need to be built among MIC in order to assure adequate access to therapy. Every country should evolve and have HPN, most should have medical and surgical rehabilitation, but few should have experienced ITx programmes in order to maintain comparable results with developed countries [27^{***}].

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Conflicts of interest

G.E.G. served as member of the Advisory Board for Shire.

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- of special interest
- of outstanding interest

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This is a remarkable and comprehensive scientific overview of the ISBTS 2015 meeting, which focuses on all aspects of intestinal failure, rehabilitation and transplantation, bringing together multidisciplinary teams of experts worldwide, to share their knowledge and experiences.