

coverage. Most medical devices in the SB category are new technology and have higher levels of clinical effectiveness and/or functions than those in the benefit category, but they are characterized as being expensive. We compare the K-NHI medical device coverage system to those in Japan and Taiwan so as to be more informed about how to cover and set prices for new medical devices.

#### **METHODS:**

We searched for materials related to medical device coverage or the reimbursement systems of three countries (Korea, Japan, and Taiwan). National health insurance laws, policy reports, and the websites of the Ministries of Health of the respective countries, for instance, were also reviewed.

#### **RESULTS:**

The NHI systems of Korea, Japan, and Taiwan have several similarities with regard to their medical device benefit lists. They reimburse listed medical devices separately although they cover them basically by including procedures or a diagnosis-related group (DRG) fee. The K-NHI reimburses for medical devices with low cost-effectiveness using the actual market medical price, similar to other medical devices in the benefit category. However, there are no detailed rules regarding how to set prices for these devices. Every listed medical device is covered at the notified price in Japan, but the prices of new medical devices with improved functions can add 1 -100 percent of the price to the notified price. The prices of devices related to new medical procedures are determined by cost-accounting methods. The NHI service in Taiwan compensates for medical devices which are alternates but clinically improved types through a balance billing method.

#### **CONCLUSIONS:**

The NHI systems in Japan and Taiwan set prices with regard to reimbursements for new medical devices separately, specifically for devices which are advanced clinically or functionally but expensive. The K-NHI must consider establishing a pricing or reimbursement system for new medical devices through the discussion

with stakeholders for reasonable reimbursements and decreasing the financial burden on the K-NHI.

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## PP012 Efficacy And Safety Of The ELIPSE Gastric Balloon For Weight Loss

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#### **INTRODUCTION:**

Conventional gastric balloons for weight loss require endoscopy for placement and removal. The ELIPSETM is a new gastric balloon designed for weight loss that is swallowed and does not require endoscopy or anesthesia. The device is designed to remain in the stomach and be expelled after a predetermined time of 4 months. The objective of this work is to assess the efficacy and safety of the ELIPSETM procedureless gastric balloon for weight loss.

#### **METHODS:**

The ELIPSETM procedureless gastric balloon was identified by the early Awareness and Alert System, "SINTESIS-new technologies," of The Instituto De Salud Carlos III (AETS-ISCIII). An early assessment of the technology was conducted. The searched databases were: MEDLINE (PubMed), Centre for Reviews and Dissemination, and the Cochrane Library. Clinical studies using the device published in any language until 10 January 2017 were reviewed.

#### **RESULTS:**

A prospective, non-randomized, open label study supported by industry was retrieved. Thirty-four patients were enrolled. Six patients treated with an experimental device were excluded. Twenty-eight patients successfully swallowed the device. No endoscopy or anesthesia was required. All devices were excreted safely. Of the twenty-five patients finally

studied, the mean percent total body weight loss was 10 percent (95 percent Confidence Interval, CI 7.3–12.7) and the mean waist circumference was reduced by 8.4cm (95 percent CI 5.7-11.8) at 4 months. Improvements were also seen in metabolic parameters (HbA1c, Low density lipoprotein, triglycerides and blood pressure). All aspects of quality of life measured by the Impact of Weight on Quality of Life (IWQoL) questionnaire demonstrated significant improvements. About safety, there were no serious adverse events or serious adverse device effects, however 64 percent of patients had vomiting, 54 percent experienced nausea, 25 percent had abdominal pain and 2 patients were excluded because of symptoms.

### CONCLUSIONS:

The ELIPSETM gastric balloon for weight loss seems to be an effective therapy with an acceptable safety profile. However it would be necessary to continue further studies to confirm these results, including comparative studies with current treatments.

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## PP013 Pain Management And Substance Abuse In Sickle Cell Disease Patients

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### INTRODUCTION:

Drug abuse is a social and public health problem because of its negative consequences of emotional and physical development in individuals. There are few studies evaluating substance abuse by individuals with sickle cell disease (SCD). These patients have severe and recurrent pain crises (1), frequently needing opioids to control it (2). The compromised quality of life can predispose this population to the occurrence of non-psychotic disorders such as depression, making them vulnerable to substance abuse (3).

### METHODS:

We evaluated the consumption of alcohol and drugs in a cohort followed at the Sickle Cell Disease Reference Center (CRAF), at Hospital de Clínicas de Porto Alegre, estimating the percentage of patients in treatment of SCD who abuse alcohol and drugs, mainly opioids. A cross-sectional study was of a convenience sample of 139 patients with SCD treated at CRAF. The pattern of substance use was evaluated using the Brazilian version of Alcohol, Smoking and Substance Involvement Screening Test (ASSIST). The exposure to opioids was measured by their use and prescription in the 24 months before the interview. The Self-Reporting Questionnaire (SRQ-20) was used to estimate the occurrence of non-psychotic disorders in this population. Descriptive analyses were performed using absolute and relative frequencies. The association between the variables was verified using the chi-square test or Fisher's exact test.

### RESULTS:

The prevalence of abusive use was 1.5 percent for alcohol and 3.0 percent for tobacco, with no abusive use of any other substance including opioids was identified. Of note was the pattern for substance use that was not influenced by exposure to substances or the presence of non-psychotic disorders.

### CONCLUSIONS:

Our data shows that use of opioid analgesics for the management of SCD painful crises is safe and does not induce substance abuse. Regular follow-up of these patients is recommended. The results of this study might be useful in other countries.

### REFERENCES:

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2. Smith WR, Dahman BA, Levenson JL, et al. Daily home opioid use in adults with sickle cell disease: The PiSCES project. *J Opioid Manag.* 2015;11(3):243-53.