Gastric Closure in NOTES Using a Novel, over-the-Scope, Nitinol Clip – A Survival Study in an Animal Model

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Introduction

Gastroscopy closure is a key consideration in NOTES. At present, there is no strong, reproducible, reliable gastroscopy closure method in NOTES. The purpose of this study was to evaluate gastroscopy closure in a survival model using a novel Nitinol clip, the “Padlock-G®” (Aponos Medical, Kingston, NH).

Abstract

INTRODUCTION: There is no reliable gastroscopy closure method for transgastric NOTES. The purpose of this study was to evaluate gastroscopy closure in a survival model using a Nitinol clip, the “Padlock-G®” (Aponos Medical, Kingston, NH).

METHODS: The Padlock-G® is a 10-mm, hexagonal, Nitinol ring with 6 inner prongs that capture and hold the gastric wall closed when the ring is deployed. The deployment pod is a 2-peeled, plastic cylinder that attaches to a standard gastroscope, extending the sleeves and the clip, which springs into its original shape and securely closes the gastroscopy. Four 20- to 40-g pigs were anesthetized and the oesophagus, stomach, and stomach were ligated with Betadine. The gastroscopy was closed by placing traction on the gastroscopy / T-tags through the scope channel, inserting the gastroscopy edges and drawing them into the deployment pod. The Padlock-G® was then deployed, securing the gastroscopy.

RESULTS: All animals thrived, ate normally, and gained weight. The 2-week survivors gained 2.6 kg each, while the 6-week survivors more than doubled in weight.

• None developed fever, tachycardia, or signs of peritoneal irritation.

• The stomachs were harvested, and inspection of the closure sites revealed excellent healing with epithelial growth over the Padlock-G®.

• There were no signs of peritoneal inflammatory, intra-abdominal adhesions, or gastric spillage. There were localized peritoneal inflammatory and intra-abdominal adhesions at the closure sites involving the T-tags but not the Padlock-G®.

• Histologic evaluation showed organizing granulation tissue with fibrosis, vascular proliferation, and mild chronic inflammatory infiltrate (scar). Acute inflammatory infiltrate was not seen.

• This study is the first successful deployment of this device in a live animal with subsequent survival.

• The Lock-IT® System with the Padlock-G® provides an effective and durable gastroscopy closure that is easy to perform.

Methods (Cont.)

• Pneumoperitoneum was created with a Veress needle.

• Two T-tags on 2-0 nylon sutures were placed on opposite sides of the gastroscopy to facilitate closure.

• The abdomen was explored with the gastroscope.

• The deployment pod and Padlock-G® were then loaded onto the end of the gastroscope. The deployment pod of the Padlock-G® was then introduced onto the gastroscopy.

• The gastroscopy was closed by placing traction on the gastroscopy / T-tags through the scope channel, inserting the gastroscopy edges and drawing them into the deployment pod. The Padlock-G® was then deployed, sealing the gastroscopy.

• All animals thrived, ate normally, and gained weight.

• The 2-week survivors gained 2.6 kg each, while the 6-week survivors more than doubled in weight.

• None developed fever, tachycardia, or signs of peritoneal irritation.

• The stomas were harvested, and inspection of the closure sites revealed excellent healing with epithelial growth over the Padlock-G®.

• There were no signs of peritoneal inflammatory, intra-abdominal adhesions, or gastric spillage. There were localized peritoneal inflammatory and adherent omentum at the closure sites involving the T-tags but not the Padlock-G®, which were on the mesocolic side. Histologic evaluation showed organizing granulation tissue with fibrosis, vascular proliferation, and mild chronic inflammatory infiltrate (scar). Acute inflammatory infiltrate was not seen.

• This study was the first successful deployment of this device in a live animal with subsequent survival.

• The Lock-IT® System with the Padlock-G® provides an effective and durable gastroscopy closure that is easy to perform.