



Figure 1. Kybella was approved this April for treatment of isolated submental fat.

Is Kybella the Next Big Thing?

One surgeon shares his insights and experience with Kybella

By Joe Niamtu III, DMD

Mesotherapy has come in and out of vogue, but it has never been mainstream. The active ingredient in many mesotherapy formulas is deoxycholic acid—which is the same ingredient in Kythera Biopharmaceuticals' new fat-dissolving injectable Kybella

Kybella received US Food and Drug Administration approval for the treatment of submental fullness in late April 2015. Although many nonsurgical niche treatments come and go, Allergan purchased Kythera for \$2.4 billion. This in itself portends big things, as Allergan obviously sees significant potential for the current on-label usage as well as future applications.

Kybella is a synthesized version of a natural bile salt that aids fat digestion. It is a cytolytic drug that, when injected into subcutaneous fat, destroys the cell membrane and produces adipolysis. The released fat is absorbed by the body.

Kybella is metabolized and excreted in the feces. Retreatment is not necessary, as the treated fat cells are permanently destroyed. The purchase price of Kybella for physicians is about \$150 per 2-mL vial.

PATIENT SELECTION AND SATISFACTION

Patient selection will be key. Kybella is

indicated for isolated submental fat deposits without skin excess. This is a limited pool of patients. Many of the patients that present for Kybella do have skin excess and are not candidates for treatment. I think that younger patients with smaller fat deposits are the optimum patients. Although submental fat can be effectively removed with a 15-minute liposuction treatment, many patients will opt for a nonsurgical treatment over liposuction.

It is important to gather standardized data for which to compare final results in patients. This should include weighing all patients before treatment. Standardized photography is also paramount. Small changes in posture, head and chin position, lighting, and background can falsely influence before-and-after pictures.

Two randomized, multicenter, double-blind, placebo-controlled studies evaluated Kybella for improvement in the appearance of submental fat. Reductions in submental fat volume were observed more frequently in the Kybella group compared to the placebo group. Results were evaluated with magnetic resonance imaging, patient discussion, and surveys. The results showed that reductions in submental fat were observed more frequently in participants who received Kybella versus placebo.

THE KYBELLA EXPERIENCE

The treatment takes about 15 minutes and is simple to perform. Skin is prepped for submental injection in the usual manner. Kybella is supplied in 2-mL vials (10 mg/mL) that are stable at room

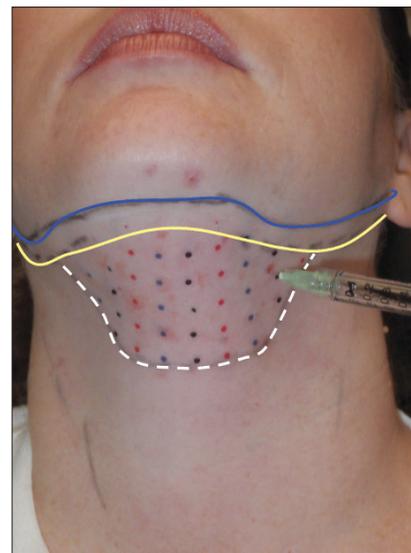


Figure 2. After applying the grid and calculating the dose, each relevant dot (within the fat deposit) is injected with 0.2 mL of Kybella.

temperature and do not require reconstitution. The average initial treatment requires two to three vials (4 to 6 mL) of Kybella, which can be up to 50 metered injections.

Follow-up treatments may require fewer injections. Treatments are repeated anywhere from 30 to 60 days apart. Two to four treatments are usually adequate, although up to six treatments can be performed.

FINDING THE SWEET SPOTS

Like any injectable, the key lies in placing the right amount of the drug in the right place and avoiding significant



Joe Niamtu III, DMD

anatomy. Patients are marked at the mandibular border, and a second marking is made about 1.5 cm below the first mark. The space between the markings is a “noninjection zone” to protect the marginal mandibular nerve. Several marginal mandibular nerve injuries were reported in trials, and all of the patients returned to normal in a mean time of 44 days.

The injector must also refrain from injecting in the submandibular and thyroid glands. The best way to do this is to target the subcutaneous fat in the submental region. Injectors must also resist the desire to inject the jowl region—again, to prevent marginal mandibular injury. No doubt, off-label usage of this drug will occur on other areas of the face and body.

Surgeons familiar with facelift and submental liposuction will have no problem identifying the exact region of excess submental fat. This area is marked, and a transfer tattoo is placed over the area of fat deposition and moistened with water. A dotted grid then transfers over the treatment region with 1 cm evenly spaced marks (Figure 2). Kybella diffuses about 1 cm, so keeping the injections evenly spaced ensures the proper dose across the treatment region.

The patient can take NSAIDs before treatment, as well as ice the area and apply topical anesthesia, if desired, on the day of treatment. The actual injections are not painful, but the region may feel hot or burn for several minutes after injection. Some surgeons inject local anesthesia before the procedure, while others do so afterward. Some injectors do not use any local at all.

To determine the dosage, the number of dots within the treatment area are counted. This is multiplied by 2, and the decimal point is moved. If the injector counts 22 dots $22 \times 2 = 44$, move the decimal = 4.4 mL of Kybella for total treatment dose. The patients I have treated have taken 3 to 5 mL of Kybella.

The injections are subcutaneous with the target into the fat deposits with a 32-gauge, ½-inch needle. About half of the needle length is inserted into the fat deposit while pinching the skin to assist palpation the actual fat, and 0.2 mL of Kybella is injected at each dot (Figure 2). Dots that are not over fat or fall outside the treatment area are not counted or injected. The actual injection time is about 5 minutes.

AFTERCARE

Post treatment includes ice packs and compression. The majority of my patients

Two to four Kybella treatments are usually adequate, although up to six treatments can be performed.



Figure 3. A before-and-after image from the Kybella FDA trials, magnetic resonance imaging frontal view.



Figure 4. A before-and-after image from the Kybella FDA trials, lateral view.

state that compression makes them more comfortable the first night. All patients will experience swelling, which progresses overnight to an edematous “wattle.” This lasts about 48 hours. Most patients will have some bruising and describe their discomfort as mild to moderate. There may be a component of paresthesia in the treatment region. The area returns to normal over 2 to 4 days.

If this treatment proves to be effective, there will likely be many other uses for other regions of the body. At present, I can also see this to be a possible treatment for post-facelift residual submental fullness. In the studies that led to FDA

approval, Kybella patients reported moderate improvements after 12 weeks, but as we gain experience with dosage, we will likely see more substantial results. ■

Ed note: This is a brand-new treatment, so I do not have personal before-and-after pictures yet. Figures 3 and 4 are company photos from the clinical trials.

Joe Niamtu III, DMD, is a cosmetic facial surgeon in Midlothian, Va, and the Secretary of the American Academy of Cosmetic Surgery. He is also on PSP’s editorial advisory board. Dr Niamtu can be reached via PSPEditor@allied360.com.